Exhibit 3

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 1 OF MDL 200:	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

Dorothy Baugher v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01053

Denise Sacchetti v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01148

Sheri Scholl, et al. v. Ethicon, Inc.
Civil Action No. 2:12-cv-00738

Lisa Thompson, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01199

Roberta Warmack, et al. v. Ethicon, Inc., et al
Civil Action No. 2:12-cv-1150

Rebecca Wheeler, et al. v Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01088

Thelma Wright v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01090

VIDEOTAPED DEPOSITION OF
S. ABBAS SHOBEIRI, M.D.

Fairfax, Virginia
February 27, 2016

Reported by: Denise D. Vickery, CRR/RMR

February 27, 2016
10:06 a.m.

VIDEOTAPED DEPOSITION OF S. ABBAS SHOBEIRI, MD, held at Gathering Room 3 of:

HYATT HOUSE MERRIFIELD
8296 Glass Aly
Fairfax, VA 22031

Pursuant to notice, before Denise D. Vickery, Registered Merit Reporter, Certified Realtime Reporter, and Notary Public in and for the Commonwealth of Virginia.

APPEARANCES

For the MDL Plaintiffs:
MOTLEY RICE LLC
26 Bridgeside Boulevard
Mt. Pleasant, SC 29464
512.695.1708
BY: MARGARET THOMPSON, ESQ.
mthompsonmd@gmail.com

For the Ethicon Defendants:
FOLIART HUFF OTTAWAY & BOTTOM
Bank of Oklahoma Plaza
201 Robert S. Kerr Avenue, 12th Floor
Oklahoma City, OK 73102
405.232.4633
BY: LARRY D. OTTAWAY, ESQ.
larryottaway@oklahomacounsel.com
BY: AMY SHERRY FISCHER, ESQ.
amyfischer@oklahomacounsel.com

Also Present:
Michael Gay, Videographer

INDEX

EXHIBITS

DEFENDANT'S

(Exhibits attached to transcript.)

PROCEEDINGS

THE VIDEOGRAPHER: We are on the record. The time now is 10:06.

This marks the beginning of disk No. 1 for the videotaped deposition testimony of Dr. Abbas Shobeiri in the matter of In re: Ethicon, Inc., Pelvic Repair Systems Products Liability Litigation.

This case is pending in the United States District Court for the Southern District of West Virginia at Charleston, MDL No. 2327.

Today's date is February 27, 2016. This deposition is being conducted at 8296 Glass Aly, Fairfax, Virginia.

Will all attorneys present please identify themselves and who they represent.

MR. OTTAWAY: Larry Ottaway and Amy Fischer here for Ethicon.

MS. THOMPSON: Margaret Thompson here for the MDL Plaintiffs.

THE VIDEOGRAPHER: My name is

Page 6

Michael Gay. I'm with Golkow Technologies. Our court reporter today is Denise Vickery, also with Golkow Technologies, and will now swear in our witness.

- - -

S. ABBAS SHOBEIRI, M.D.,

called for examination, and, after having been duly sworn, was examined and testified as follows:

THE VIDEOGRAPHER: You may proceed.

EXAMINATION

BY MR. OTTOWAY:

Q. Would you state your name please for the court and jury?

A. Abbas Shobeiri.

(Document marked, for identification purposes, as Defendant's Exhibit No. 1.)

BY MR. OTTAWAY:

Q. Dr. Shobeiri, my name is Larry Ottaway. I represent Ethicon. For purposes of your deposition here today, I've put in front of you a document which I've marked as Defendant's

Page 7

Exhibit 1.

Have you seen that document before?

A. No. First time.

Q. Okay. The document asks on roughly page 5 for you to bring documents with you today.

Have you brought any documents with you today?

A. No. Except for this.

Q. May I see what --

A. Sure.

Q. -- you brought?

A. (Handing document).

Q. Doctor, you understand we are here today to take your deposition as an expert for the plaintiffs regarding TVT-O.

Is that -- if I say "TVT-O," do you know what I mean?

A. Yes.

Q. Okay. Can you tell the ladies and gentlemen of the jury what that abbreviation stands for?

A. It's tape TVT obturator, tension-free vaginal tape obturator.

Q. Okay. And today I'm going to try to

Page 8

limit my questions to that product.

Fair enough?

A. Fair.

Q. So if I ask you a question, please assume it's related to that. And if it's not, you tell me if you need to wander into another area, and we'll know on the record then that you're referring to that. Okay?

A. Yes.

Q. Now, you're here today to testify about Ethicon's TVT-O.

Have you also spent some time reviewing other, what I'll call, obturator products?

A. Yes.

Q. Have you written reports regarding other TVT-O type products?

MS. THOMPSON: Object to form.

BY MR. OTTAWAY:

Q. When she does that, Doctor, you can go ahead and answer the question, and it's only if she tells you not to answer a question that we'll have a discussion.

Fair enough?

Page 9

A. Fair.

Q. Okay. So my question was: Have you written reports about other TVT-O products not manufactured by Ethicon?

A. No.

Q. Expand that out a bit.

Have you written reports of TVT products not of Ethicon's manufacture?

MS. THOMPSON: Object to form.

THE WITNESS: No.

BY MR. OTTAWAY:

Q. No. Okay.

Have you testified before about TVT products generally?

MS. THOMPSON: Object to form.

THE WITNESS: What do you mean by "TVT products"?

BY MR. OTTAWAY:

Q. Transvaginal tape or mesh products.

A. So you just changed question.

Or mesh?

Q. Transvaginal tape or mesh.

A. So vaginal mesh?

Q. Yes.

Page 10

A. Yes.
Q. Okay. And have that -- that testimony been against or, no, relating to products manufactured by Ethicon and other manufacturers?
A. Other manufacturers.
Q. Okay. Would those other manufacturers include Boston Scientific?
A. I believe so.
Q. Bard?
A. I believe so.
Q. American Medical Systems?
A. I don't recall, but probably.
Q. Okay. Have you ever rendered an opinion in any of those cases that the products were safe and effective?
A. The vaginal mesh?
Q. Yes.
A. So you're asking me if I rendered an opinion that vaginal mesh was safe and effective?
Q. Yes.
A. No.
Q. Okay. Do other manufacturers make products similar to TVT-O, the product made by

Page 11

Ethicon?
A. Could you expand on that?
Q. Well, I'll try, and please understand, Doctor, I'm not a physician. So you're going to have to give me the benefit of the doubt when I ask some questions because I may not know the terminology that you use.
Fair enough?
Tell me how you understand the TVT-O product line differs from other transvaginal meshes.
A. So you're mixing up terminology now. So that's confusing me because you're --
Q. I don't want to confuse you. I want you to tell me what terminology you wish to use.
A. Well, you just said compare TVT-O to vaginal meshes; right? So vaginal mesh is produced to go under the bladder or the rectum, and the TVT-O is a sling.
Q. Okay. And do they differ in the way they are implanted?
A. Some are.
Q. Okay. Tell me in your terminology how those differ.

Page 12

A. So could you be specific on which mesh products you're talking about?
Q. Well, let's talk about mid-urethral slings.
A. Okay.
Q. And then the -- you knew what I meant when I said TVT-O, the Ethicon product; correct?
A. Okay.
Q. Tell me about how those differ in the way they are implanted.
A. So you want me to tell the difference between TVT-O and mid-urethral slings?
Q. Yes.
A. Do you have a specific mid-urethral slings that you want to --
Q. No. You can pick any one you want.
A. So I'm just trying to think which one. So you want to compare it to TVT?
Q. Sure. If that's --
A. All right. So TVT is a retropubic sling and TVT-O is an inside-out transobturator sling.
Q. So the difference in your mind

Page 13

between the two is the way they are implanted; one is retropubic and the other is transobturator?
MS. THOMPSON: Object to form.
THE WITNESS: The path they take.
BY MR. OTTAWAY:
Q. The path they take. Fair enough.
And can you explain to the ladies and gentlemen of the jury the difference in the path surgically that's taken between those two types of devices?
A. Yes. The retropubic slings go behind the pubic bone and then come out above the pubic area, and the transobturator inside-out slings go through the vagina and come through the obturator -- obturator space and come through the inner thigh.
Q. Okay. Now, you refer to the transobturator inside-out.
A. Uh-huh.
Q. Is that --
A. Yes.
Q. -- the type we're talking about here today?

Page 14

A. We are talking about the TVT-O product.
Q. Right. Which is an inside-out --
A. Yes.
Q. -- surgical technique?
A. Yes.
Q. Are there other transobturator products which are inside-out?
A. Slings?
Q. Yes.
A. Not exactly the same, but there are -- there are some other ones.
Q. And can you give me a list of the ones you have in your mind when you say that?
A. So, for example, the TVT-Secur.
Q. Okay.
A. You know, and the variation of the TVT-O, which is the sort of next generation -- generation preview. Those are some.
Q. Now, is there also an outside-in transobturator sling?
A. Yes.
Q. And who manufactures that product?
A. Boston Scientific. Mainly everybody

Page 15

pretty much. Bard.
Q. Okay. Do you have an opinion about whether the outside-in transobturator products are safe and effective?
MS. THOMPSON: Object to form.
THE WITNESS: Could you narrow down your question? It's very broad.
BY MR. OTTAWAY:
Q. Well, I'm not sure I can.
A. Uh-huh.
Q. Do you believe that transobturator products that use the outside-in implantation technique are safe and effective?
MS. THOMPSON: Object to form, and it's the combination of the "safe and effective" in the same -- in the same.
BY MR. OTTAWAY:
Q. You can divide that up if you want. Do you believe they are safe?
A. They have their own set of problems.
Q. Have you ever testified that they are safe?
A. Not that I remember.
Q. Have you held the opinion that they,

Page 16

in fact, are defective?
A. You mean do I have an opinion about it?
Q. Yes. Do you have an opinion about it?
A. They have their own set of problems.
Q. I'm not sure that was an answer to my question, Doctor.
A. Uh-huh.
Q. Do you have an opinion that they are defective?
A. Could you define "defective"?
Q. Any way you want to use it. In your own terminology.
A. So would I be using transobturator tapes? Is that what you're asking or --
Q. Sure. Go ahead if you want to answer it that way.
A. I think that generally we try to restrict ourselves to the retropubic TVT type products.
Q. Okay. So in your practice, you don't use any transobturator products, whether it's inside-out or outside-in.

Page 17

Fair statement?
A. Well, I used to use TVT-O, but patients had problems and I stopped it. And I used to use the transobturator tapes, and patients had problems and I stopped it.
Q. So the answer to my question is: You do not use any transobturator product now?
A. No, because the patients have problems.
Q. Okay. Doctor, I appreciate and I'm not trying to limit your answers, but if you would answer my question, this would go quicker.
A. Uh-huh.
Q. Fair enough?
A. Fair.
Q. Okay. When did you stop using transobturator products, whether of the inside-out surgical technique or outside-in technique?
A. The -- we used the transobturator tapes -- I used the transobturator tapes when they initially came out, and for me they had, you know, issue with mesh erosion, which I didn't like. So we went to -- I went to TVT-O and that

Page 18

had its own complications, and we didn't like it.
So in terms of when we stopped it, I probably stopped using TOTs -- I'm just going by memory -- probably about five -- five years ago or so, and I may have used TVT-O for about three years or so before I stopped that.
Q. When did the transobturator products come on the market; do you remember?
MS. THOMPSON: Object to form.
THE WITNESS: Hmm. Well, they have been on the market probably as early as 2000s, somewhere about that.
BY MR. OTTAWAY:
Q. And as I understood your testimony, you said you stopped using them in 2011 or so?
A. Well, I switched to the TVT-O at that point.
Q. Okay.
A. Yeah.
Q. And how long did you use TVT-O after 2011 before you stopped using it?
A. Hmm. Probably about a few years, three, four years.
Q. So maybe 2013 or '14?

Page 19

A. No, no. We -- I think I -- so it was sequential where we were -- where -- where I was using TOTs probably up to 2010 or so and then switched to TVT-O for a few years.
Q. Again, so if you stopped using the others and started using TVT-O by Ethicon in 2010 and used it for a couple of years, would your testimony and best recollection be that you used the TVT-O product up until about 2012 or '13?
A. That's probably true.
Q. All right.
A. Let me see. It's 2016 now. Yeah.
Q. Fair?
A. Fair.
Q. Okay. And during the period of time you used transobturator products in general --
A. Uh-huh.
Q. -- how many implants did you perform?
A. So we are talking about the TVT-O?
Q. Any of the transobturator products, and then I'll narrow it to TVT-O.
MS. THOMPSON: And the transobturator products? Slings?

Page 20

MR. OTTAWAY: Yes.
MS. THOMPSON: Okay.
MR. OTTAWAY: Yes, and I think the doctor knows that's what I'm referring to. I asked him at the beginning of the deposition to limit his testimony to the TVT-O sling.
THE WITNESS: Well, actually, I was thinking about the same thing.
BY MR. OTTAWAY:
Q. Good. Okay.
A. So, yeah, we still use the trans- -- I use the transobturator tapes infrequently. Mainly use it in patients that I felt like they may have had retropubic scarring or prior surgeries where using the TVT would increase their risk of bladder injury.
So I cannot give you a number in terms of. I would say the transobturator tapes are probably more than 50. Is that fair?
Q. I'm having to rely on you, Doctor, and your memory.
So somewhere around 50 you think?
A. 50? It's probably fair to say more

Page 21

than 50.
Q. More than 50. Okay.
And of the 50, how many were TVT-O?
A. Well, these were just probably TOTs. So then -- then I switched to TVT-O.
Q. Okay. And how many TVT-O procedures did you perform?
A. Probably more than 30.
Q. So roughly 50 and roughly 30, about 80 total?
A. I'm guessing. Could be more.
Q. Give me the parameters, Doctor. I just -- I'm not trying to hold you to specific number.
A. Uh-huh.
Q. I just want to know roughly your best guess.
A. Hmm. I think it's fair to say I have performed -- I performed more than 50 TOTs, and it's fair to say that I performed more than 30, upwards of 50 TVT-Os.
Q. Okay. So that would take you somewhere up around a hundred total?
A. It's a good guess.

Page 22

Q. All right. Now, you stopped using the TVT-O in 2012 or '13, roughly.
A. Uh-huh.
Q. Did the product remain on the market and available to surgeons after you stopped using it?
A. I believe so.
Q. In 2012 or 2013, as I recall your resumé, you were at the -- in Oklahoma at an institution, were you not?
A. True.
Q. What institution was that?
A. At the University of Oklahoma.
Q. And at the University of Oklahoma, were there other physicians in your profession and specialty that continued using TVT-O after you stopped using it?
A. Hmm. Actually, my partners at the university had reservations using TVT-O. So they never actually used TVT-O, and they are not using TVT right now.
Q. Okay. So it's your testimony that your partners at OU are not using TVT-O?
A. They may have picked it up since

Page 23

then, but they were not using it before and I doubt that they're using it now.
Q. Okay. How about people outside your association partnership?
A. Uh-huh.
Q. In Oklahoma, were surgeons in your specialty using TVT-O in Oklahoma while you were there and after you stopped using it?
A. Yeah, I'm sure they were because we're getting a lot of their complications and that was. So I know that Ethicon was heavily marketing it, and they -- they were using it in the community.
Q. Okay.
A. We were getting the complications.
Q. And you left Oklahoma when?
A. In 2015.
Q. Okay. And where did you alight after you left Oklahoma?
A. Pardon me?
Q. Where did you end up after you left Oklahoma?
A. Here.
Q. And we're talking about here in the

Page 24

Washington, DC area?
A. Northern Virginia.
Q. Okay.
A. I'm at the Inova Health Care.
Q. Okay. Tell me about Inova. What is Inova and your job with Inova?
A. Inova is a mile down the road from here. When you drive down, you can see one of their hospitals. It's a hospital system with five, six hospitals serving Northern Virginia. It's the Northern Virginia campus for Virginia Commonwealth University.
So I'm a professor of OB-GYN for Virginia Commonwealth University. I'm a professor of OB-GYN at George Washington University. I'm a professor of OB-GYN at OU still, and I'm a professor of cellular biology and anatomy at OU still.
Q. And does the Inova Hospital chain that you've described have physicians in your specialty who use TVT-O?
A. No.
Q. Okay. Does the University of Virginia Commonwealth have a hospital associated

Page 25

with it?
A. I'm not aware of that.
Q. Don't know one way or the other?
A. It's in Richmond. I haven't been down there.
Q. Okay. And is TVT-O a product that is available to surgeons to use in the Inova Hospital chain?
A. I know at Inova Fairfax Hospital where we are it's not.
Q. Okay. Are you aware of the other hospitals in the Inova chain?
A. I have not seen it on our inventory -- inventory.
Q. Okay. In the teaching situation where you are, do you teach medical students residents or fellows the surgical technique for implanting transobturator devices?
A. And what's the question?
MR. OTTAWAY: Can you read that one back to him? I don't know that I can ask it any better.
(The reporter read the record on page 25 lines 15-18.)

Page 26

MS. THOMPSON: I'm going to object to the form on that. Sorry I didn't hit it the first time.

THE WITNESS: I'm not doing them, so I cannot teach them. But, again, I may elect to do one if there's a patient who, for example, has had severe retropubic scarring, ureteric implantation, cancer radiation in that area where I think it's the last choice that I have.

BY MR. OTTAWAY:

Q. Are there -- are the students at the Virginia Commonwealth Medical School taught how to implant transobturator devices, whether by you or someone else?

A. Medical students are observers. So we don't teach medical students how to implant any devices.

Q. Okay. Where do they learn that if they don't learn it from you?

A. They choose to do residency in OB-GYN or urology, and then they learn it during their residency.

Q. Okay. So do I understand then that

Page 27

residents in your specialty learn how to implant transobturator devices while at your institution?

MS. THOMPSON: Object to form.

THE WITNESS: No, they learn how to do retropubic devices.

BY MR. OTTAWAY:

Q. Okay. And retropubic devices only?

A. As I said, they -- there may be a few transobturators a year for whatever extreme situation, but it's not the norm.

Q. If your institution doesn't have available to it TVT-O, how would you get it if you decided you wanted to use it for a particular patient?

A. We won't.

Q. Sorry?

A. So you need to be clear with your terminology. Are you using TOT and TVT-O interchangeably?

Q. Okay. You tell me. I don't want to use things interchangeably that are confusing. So you tell me.

A. So --

Q. Transobturator tape.

Page 28

A. Uh-huh. It's very different with TVT-O.

Q. Okay. And you tell me the difference that you perceive in the two.

A. They take different paths.

Q. Okay.

A. The path for the TVT-O is inside-out and the TOT is outside-in.

Q. Okay.

A. So they are different devices.

Q. And do you -- do you prefer one over the other?

A. Well, I'm really not doing TVT-Os. TVT-Os at Fairfax are available on the shelf, and people are using it very sparingly.

Q. Okay. How about TOTs?

A. That's what I'm talking about, the TOTs. There are no TVT-Os on the shelf --

Q. Okay.

A. -- at Fairfax.

Q. I think we spoke over each other there because I thought you said TVT-O was available.

But what you were saying was TOT,

Page 29

that is the outside-in, is but TVT-O, the inside-out, is not?

A. I think the question you asked me earlier was whether there's TVT available at Fairfax. I said no. And you said is it available anywhere on the system, and I say I have not seen it on the inventory.

Q. Okay. And how about TOT then?

A. And what I answered was that TOT is on the shelf, and we are using it very sparingly.

Q. Okay. Let me ask you a few questions, Doctor.

Do you hold any patents in medical devices?

A. No.

Q. Have you ever designed a medical device for surgical implantation?

A. I have, but we have never -- I have never gone down to really patent them.

Q. Okay. Tell me about the device you designed.

A. Well, we didn't patent it but -- and we didn't use it surgically. So, for example, devising Q-tips used for measurement of POP-Q.

Page 30

Devising retractors to help during sacrocolpopexies, you know.
Q. Okay. But those have not been used?
A. Quite honestly, those are the things I devised and by the time that I decided it would be a good time to patent them, they -- somebody else beat them to the market.
Q. Have you ever designed a mid-urethral sling?
A. Have I ever designed a mid-urethral sling? Well, we -- we create -- I created ultrasound Phantoms, and we did cut like sling tapes that we implanted into the Phantoms.
Q. Okay. Well, I'm going to get into your ultrasound opinions here in a minute, but right now I'm asking: Did you ever design for use in a patient a mid-urethral sling?
A. Well, are you talking about a synthetic sling?
Q. Sure.
A. No, I have not designed a synthetic sling that has gone to the market.
Q. Okay. And have you ever designed a device which has been implanted into a patient

Page 31

that has been approved or vetted by the FDA?
A. No.
Q. Are you an expert in FDA regulatory matters?
A. I know a lot about FDA regulatory matters.
Q. My question was: Do you consider yourself an expert in FDA regulatory issues?
A. Could you define "expert"?
Q. You -- you're the one that mentioned it. I'm just asking you if you consider yourself to be an expert in FDA regulatory matters.
A. I know more than a lot of other people.
Q. Okay. Have you worked -- been hired by the FDA to work on regulatory issues?
A. No.
Q. Have you ever worked with a device manufacturer to gain FDA approval for a medical device?
A. Yes.
Q. Okay. Tell me about that.
A. I'm not sure if I can because we signed confidentiality agreement.

Page 32

Q. Well, obviously I don't want you to violate a confidentiality agreement.
A. Uh-huh.
Q. But you're going to have to give me some idea for whom, when, what in general was involved.
A. Hmm. AMS.
Q. Okay. Tell me about what you did for AMS in general.
MS. THOMPSON: Only to the extent that you can under your agreement.
THE WITNESS: Well, we trialed the -- we trialed TOPAS.
BY MR. OTTAWAY:
Q. Trialed? I'm sorry. Trialed TOPAS?
A. Uh-huh. T-O-P-A -- is it S or Z? I don't know. I think that's it.
Q. Okay. And what is TOPAS?
A. It's a fecal incontinence product.
Q. And does it involve any kind of synthetic mesh?
A. Yes.
Q. Okay. What kind of mesh product is used in TOPAS that you were involved with?

Page 33

A. Well, we -- it was their -- their version of polypropylene.
Q. And how is it -- how does it differ from a polypropylene used in TVT-O if you know?
A. It's just the way it's woven is probably different.
Q. Okay. And tell me how the way it is woven is different than TVT.
A. So, for example, TVT-O when you implant it and it frays and the little pieces of mesh come undone, you can actually see it on your hand. That is, when you pull the sheet out, the sling rolls into sort of tubular structure and, you know, just as it gets stretched, the -- the holes in the mesh are not as the size that they were designed. So -- so it's just different.
Q. Okay. And, again, how is it different? I'm -- I'm -- is it --
A. So the TVT-O when you insert it, when you take the plastic sheet out, you know, it frays. The little piece of mesh can come on your hand and then it can also roll, and also it stretches where the holes that are there sort of become smaller.

Page 34

Q. Right. You told me that, but I want to know how the polypropylene used in TOPAS differs from the polypropylene used in TVT-O.
A. It's just different design.
Q. Okay. And how is the design different?
A. The -- the weave is different.
Q. Okay. Weave.
A. Uh-huh.
Q. Anything else?
A. I think that's mostly what differentiates them, and also the -- just the way it designed. It's not -- doesn't stretch like TVT-O.
Q. Okay. So its application is different?
A. No. It's just woven differently, so it wouldn't be as stretchy.
Q. Does it differ -- differ in chemical property?
MS. THOMPSON: Object to form.
THE WITNESS: The chemical property. The polypropylene? When you say "chemical property," like is it like made

Page 35

differently or --
BY MR. OTTAWAY:
Q. Yes.
A. -- what do you mean?
So, no, it's polypropylene and it's just woven differently.
Q. All right. Is TOPAS on the market?
A. It -- well, it has gone through its FDA trial, and I believe it just got a hearing recently.
Q. Okay. What exactly was your role in the trial for TOPAS mesh?
A. I studied the anatomical course of the sling, both in cadavers and in live patients, with ultrasound, and we did the trials.
Q. Okay. Were you involved in preparing any written materials that were to accompany or are to accompany TOPAS if it's released to the market?
A. Could you repeat that question?
MR. OTTAWAY: Can you read that back to him again? I'm not sure I can ask it any better.
(The reporter read the record on

Page 36

page 35 lines 16-19.)
THE WITNESS: I haven't looked at their final material but, I mean, we did their anatomical studies.
BY MR. OTTAWAY:
Q. Okay. So is the answer to my question you have or have not prepared written materials that will go with the product if it is released to the market?
A. I gave them reports. So what they are using, it is their prerogative.
Q. Okay. Well, for example, have you ever prepared a warning or IFU that would accompany a device --
A. No.
Q. -- on the market? No?
A. No.
Q. Okay. Did you do that for or were you asked to do that by AMS for TOPAS?
MS. THOMPSON: Object to form.
THE WITNESS: No.
Thanks.
BY MR. OTTAWAY:
Q. Have you ever written a warning for

Page 37

any product?
MS. THOMPSON: Object to form.
THE WITNESS: Have I ever written a warning for any products? No.
BY MR. OTTAWAY:
Q. Have you ever had any special education about warnings and how they should be written?
MS. THOMPSON: Object to form.
THE WITNESS: Well, I have read a lot of IFUs and in medical school we, you know, we learn about these things.
BY MR. OTTAWAY:
Q. Well, other than your medical school training and reading IFUs, have you had any specialized training in the preparation or dissemination of warnings?
A. Could you expand on that?
Q. Not really.
A. Uh-huh.
MR. OTTAWAY: You want to ask it? Read the question again.
(The reporter read the record on page 37 lines 14-17.)

Page 38

MS. THOMPSON: Object to form.
THE WITNESS: So like have I gone to law school or --
BY MR. OTTAWAY:
Q. I know you haven't been to law school because I've read your resumé.
A. Uh-huh.
Q. My question stands as asked. Can you answer it?
A. Besides the training I have had, I have not had any other training.
Q. So confined to what you learned in medical school and in reading IFUs?
MS. THOMPSON: Object to form.
THE WITNESS: Yes. I'm not a lawyer.
BY MR. OTTAWAY:
Q. Are you a member of the -- what I'll refer to as -- AUGS? If I say "AUGS," do you know what I mean?
A. Yes.
Q. Okay. What -- what, for the ladies and gentlemen of the jury, is AUGS?
A. The American Urogyne Society.

Page 39

Q. How long have you been a member of that organization?
A. Probably close to 20 years.
Q. Have you reviewed abstracts for that organization and prepared programs for that organization?
A. Yes.
Q. Are you a member of the American College of Surgeons?
A. Yes.
Q. Gynecological surgeons.
What I will refer to as ACOG?
A. They're different. College of Surgeons and ACOG are different.
Q. And are you a member of both?
A. Yes.
Q. And when you say "ACOG," can you tell the jury what you're referring to?
A. American College of Obstetricians and Gynecologists.
Q. How long have you been a member of ACOG?
A. Probably 25 years.
Q. Do you agree with me that stress

Page 40

urinary incontinence can and does adversely affect the quality of life for women?
A. I agree with you.
Q. Do you agree with me that mid-urethral slings are the standard of care for the treatment of stress urinary incontinence?
MS. THOMPSON: Object to form.
THE WITNESS: The surgical standard of care, yeah.
BY MR. OTTAWAY:
Q. Okay. Is that position shared by the organizations we just mentioned of which you are a member, AUGS and ACOG?
A. I think those are the standard of care, yeah.
Q. And would you agree with me that TVT-O is a type of mid-urethral sling?
A. That's debatable whether it ends up in mid-urethral or not.
Q. Do you believe it's a mid-urethral sling or not?
A. I believe it's not placed mid-urethral.
Q. Okay. Have either AUGS or ACOG

Page 41

taken a position that TVT-O is not a mid-urethral sling?
A. Let me correct myself.
In the TVT-O IFU, where they say to make the incision does not facilitate putting the sling in mid-urethral. ACOG and AUGS support mid-urethral slings.
Q. Have ACOG or AUGS taken a position, to your knowledge, indicating that TVT-O is not within the category of mid-urethral slings?
A. I believe they have not delineated that.
Q. All right. We've been going about 45 minutes, Doctor. Let's take a break.
And anytime you need to take a break, by the way, if you'll just answer the question on the table and tell me you need to take a break, we'll do it at your convenience as well.
Fair enough?
A. That's great.
MR. OTTAWAY: Okay.
THE VIDEOGRAPHER: Time now is 10:49. We are going off the record.

Page 42

(Recess - 10:49 a.m.
- 11:02 a.m.)
THE VIDEOGRAPHER: The time now is 11:02. We are back on the record.
BY MR. OTTAWAY:
Q. Doctor, just going back to cleaning up a few things and we'll move on to another topic.
We've established that both TOT, transobturator tape, and TVT-O are still on the market for treatment of stress urinary incontinence; correct?
MS. THOMPSON: Object to form.
THE WITNESS: True.
BY MR. OTTAWAY:
Q. And that you in the past have used both?
A. True.
Q. Are you aware of any of your patients that are still benefiting from TVT-O?
A. So am I still aware of patients that are benefiting from the TVT-O?
We saw some that came with problems, you know, but then there are others who could be

Page 43

having problems and have gone to other physicians. But the ones who haven't had problems, I'm assuming they have benefited from it.
Q. And we talked about the fact that you would still occasionally use a transobturator product if you felt in a particular patient that the risk/benefit profile favored its use; correct?
A. If I'm, you know, if I'm 90 percent, 100 percent sure that they would get into the bladder doing a retropubic approach, whether it's synthetic device or whether it's patient's own tissue, and that's the only alternative I have, then that overweighs the risk/benefit ratio.
Q. Okay. And when was the last time you made such a decision and used a transobturator product?
A. Probably three years ago.
Q. Okay. Now, when you're looking at the risk/benefit profile of a transobturator product versus a retropubic product, what are the advantages of the transobturator approach, whether it's inside-out or outside-in?

Page 44

MS. THOMPSON: Object to form.
THE WITNESS: The main risk that we are trying to avoid is getting in the patient's bladder, and as I said, I'm very sure that that can be a problem that would -- that would overweigh. But most often I can suture the tissue under the urethra to do the same thing.
That's why I haven't really needed to do a transobturator tape for the past few years.
BY MR. OTTAWAY:
Q. Is that the perceived benefit of a transobturator approach is that you are more likely to avoid injury to the bladder?
A. Originally when they designed it, that was their intent.
Q. Okay. Now, you've written a report concerning TVT-O and it has been provided to me. You remember doing that?
A. Yes.
Q. I think it's dated February the 1st of this year or just a few weeks ago?
A. True.

Page 45

Q. When did you begin preparation of that report?
MS. THOMPSON: Object to form.
BY MR. OTTAWAY:
Q. Again, Doctor, you're free to answer.
A. Probably four to six weeks before that.
Q. So late 2015 or early 2016?
A. Hmm. Probably.
Q. Who asked you to prepare that report?
A. Motley Rice.
Q. Okay. So that report was prepared solely for use in litigation. It wasn't prepared for any other reason?
A. Yes.
Q. As I understand it, you charge for your services?
A. Yes.
Q. Charge being $750 an hour?
A. Yes.
Q. And $6,000 a day plus expenses for testimony?

Page 46

A. True.
Q. So today are we on the $750 an hour or the $6,000 a day plus expenses?
A. 6,000 divided by half because we'll be utilizing half a day.
Q. So $3,000 for half a day?
A. Yes.
Q. And did you prepare this report yourself?
A. Yes.
Q. Okay. It's got an Appendix B associated with it, which is a list of reliance materials.
A. Hmm?
Q. A list of reliance materials.
A. Okay.
Q. Did you assemble those yourself?
A. The references? Yes.
Q. Okay. Now, part of those references are what I have marked as 2.
(Document marked, for identification purposes, as Defendant's Exhibit No. 2.)
BY MR. OTTAWAY:

Page 47

Q. And for your benefit, Doctor, I will tell you those are documents that have been produced by Ethicon in this litigation.
A. I'm just going over them.
Q. Of course. Take your time.
A. (Reviewing document). Yes.
Q. How did you get those documents?
A. It was sent to me.
Q. By?
A. Motley Rice.
Q. Do you know how many documents have been produced in this litigation by Ethicon?
A. How many what?
Q. Documents have been produced by Ethicon in this litigation?
A. Not really.
Q. Did you go through additional documents and cull those out, or were those the documents that were provided to you?
A. I went through all the documents that was provided to me. I went over this because making sure that I had seen this before.
Q. Okay. And other than those documents in front of you, have you reviewed any

Page 48

other documents produced by Ethicon in this litigation?
A. Not that I recall.
Q. So as I understand it, those in front of you are the ones you've reviewed and you've reviewed no others?
A. Unless I quoted them in my report.
Q. Okay. Those are the ones I think you mention in your report.
A. Then that's what it is.
Q. Okay. Now, you made no independent effort to go through other documents produced by Ethicon in this litigation?
A. No.
Q. Some of those documents were originally in French. I don't know whether you speak French. Do you?
A. No.
Q. Okay. Who provided the translations of those documents for you?
A. I haven't skimmed over those.
Q. Please, you're free to look at them anytime you want.
A. Hmm. So this document you're

Page 49

talking about is on which page? Are you talking about this one?
Q. There are two that are translated from French into English in whole and part.
A. Uh-huh.
Q. I just wanted to know whether you did the translations or who did them.
A. That's how they came.
Q. Okay. And the literature portion of Exhibit B, did you assemble that yourself?
A. The ones that I have quoted?
Q. Yes.
A. Yes.
Q. Okay. When we talk about literature, Doctor, is there a hierarchy of literature that physicians rely upon, some more reliable than others?
A. Could you refine it?
Q. Yeah, that was a terrible question. You're right to ask me to repeat it.
If you as a physician review literature, do you in your own mind differentiate between, say, peer-reviewed random controlled trials and individual case studies?

Page 50

A. Each of them are valuable in their own way.
Q. Is there a hierarchy in your mind that one is more reliable or better than another?
A. I won't discount the case studies. Because if you are talking about a problem that is very major, so not all the side effects are created equal, and you cannot judge them based on numbers.
Q. Okay. And I'm glad you answered that, Doctor, but my question was: Is there a hierarchy of those kinds of studies that you consider one more reliable than another?
A. Depends on your end point.
Q. Okay. Well, let's take an end point of determining whether a medical device is safe and effective. Do you --
MS. THOMPSON: Object to form and asked and answered.
BY MR. OTTAWAY:
Q. You're free to answer the question if I can get it out, Doctor.
The question is pretty simple. I'm not trying to be difficult.

Page 51

Do you consider random controlled trials more persuasive than individual case studies as a general rule?
A. Depends on your end point.
MS. THOMPSON: If you can answer -- if you can answer that question that way.
THE WITNESS: Yeah. So, again, it depends on your end point.
BY MR. OTTAWAY:
Q. Okay. Well, let's take the end point of trying to determine whether a product is safe and/or effective.
Do you distinguish in your mind between those two types of articles?
MS. THOMPSON: Object to form. Combining the safe -- safety and effectiveness.
THE WITNESS: So one reason that, for example, the TVT-O or the transobturator approach was thought of or envisioned was because there was bowel injury associated with TVT type slings.
There are very few of them in the

Page 52

literature, and there are some in MAUDE database of FDA. So if you want to look at numbers, you know, you cannot equate them.
You can have a side effect, you can have a complication that is very bad, and those few numbers really would sway you to other things. So it's just not by pure numbers that you can go in terms of safety of a device.
BY MR. OTTAWAY:
Q. Okay. Again, I appreciate your answer, Doctor, I really do, but my question was about the peer-reviewed literature.
MS. THOMPSON: He answered the question.
MR. OTTAWAY: Counsel, are you instructing him not to answer?
MS. THOMPSON: No. No. I'll object. Asked and answered.
MR. OTTAWAY: Thank you, counsel.
BY MR. OTTAWAY:
Q. Go ahead, Doctor, I'm sorry.
In your mind, is there a hierarchy of peer-reviewed literature, some of which you

Page 53

consider more important or persuasive than others?
A. Depends on your end point.
Q. Okay. Again, taking my end point, do you consider one of those a random controlled trial or an individual case study more persuasive?
MS. THOMPSON: Object to form.
BY MR. OTTAWAY:
Q. You may answer.
A. Each of them have values.
Q. Okay. And in your mind the same?
A. I read them and they're all important.
Q. Okay. And do you, for example, Doctor, accept certain peer-reviewed journals as authoritative?
A. Pardon me?
Q. Do you -- for example, the European Journal of Obstetrics and Gynecology, do you review that document?
A. The American Journal for OB-GYN or --
Q. European Journal of Obstetrics and

Page 54

Gynecology.
A. European Journal of OB-GYN?
Q. Yes.
A. What about them?
Q. Is that a journal that you consider authoritative?
A. I have read their articles.
Q. Okay. And do you rely on them in your practice?
A. I would read the articles critically. And if you have an article to show me, I can read them -- read it and tell you what I think about it. I may have reviewed a few papers for them.
Q. How about the American College of Obstetrics and Gynecology, publications by them? Do you consider those authoritative and reliable generally?
A. I'm a reviewer for them.
Q. Okay.
A. But that doesn't mean that some bad papers don't make it into the journal.
Q. That's why I said: Generally do you consider them to be a reliable reporting source?

Page 55

A. You read each -- each report critically, yeah.
Q. Same true of the International Journal of Gynecology?
A. Absolutely.
Q. Journal of Urology?
A. Any journal you want to read the article and judge it based on its merit and the end point that you are trying to evaluate.
Q. Practice bulletins issued by AUGS, the organization we spoke of previously?
MS. THOMPSON: Object to form. What's the question?
BY MR. OTTAWAY:
Q. Do you consider those to be generally reliable and informative?
MS. THOMPSON: Object to form.
THE WITNESS: There are -- they provide -- so you're talking about the which one? The ACOG bulletin?
BY MR. OTTAWAY:
Q. AUGS.
A. So AUGS.
MS. THOMPSON: Object to form.

Page 56

THE WITNESS: What about AUGS?
BY MR. OTTAWAY:
Q. Do you consider their practice bulletins to be generally reliable and informative?
MS. THOMPSON: Object to form.
THE WITNESS: Does AUGS have practice bulletin?
BY MR. OTTAWAY:
Q. Do you know?
A. I'm thinking that you're getting ACOG and AUGS mixed up.
Q. It's quite possible. I get confused all the time, Doctor, but I think my question there was pretty specific.
Are you aware of AUGS issuing practice bulletins?
MS. THOMPSON: Object to form.
THE WITNESS: They have statements.
BY MR. OTTAWAY:
Q. Okay. And do you consider those statements to be generally reliable and informative?

Page 57

MS. THOMPSON: Object to form.
THE WITNESS: It would be opinion. Do you have a specific one that you want me to look at?
BY MR. OTTAWAY:
Q. I'm just asking in general.
A. I would look at it and give you my opinion.
Q. Okay. Do you agree that there is a body of peer-reviewed literature containing random controlled trials that finds that TVO is safe and effective?
MS. THOMPSON: Object to form.
THE WITNESS: Do I agree that there is a body of literature that shows TVT-O is safe and effective?
Each article tells you something different. Some of them point to efficacy. Some of them look at -- depending on how they are designed, they may look at the side effects of the device. So it depends on really how the study was designed. You cannot put all of them together.
BY MR. OTTAWAY:

Page 58

Q. Can you answer my question?
A. I just -- yes.
Q. Are you aware of a body of peer-reviewed literature that finds that TVOT is safe and effective?
MS. THOMPSON: Asked and answered and object to form of the question.
BY MR. OTTAWAY:
Q. TVT-O, yes.
A. So is there specific literature you want me to review or point at or --
Because one thing that I told you is that you cannot look at all the complications equally. Some of them can be so horrendous that that would be a bad safety issue.
Q. So are you unable to answer my question as asked?
A. Could you repeat the question?
Q. Ma'am, can you? I hate to ask you to do that again, but I'm not sure I can repeat it exactly the same way.
(The reporter read the record on page 58 lines 3-5.)
BY MR. OTTAWAY:

Page 59

Q. TVT-O.
MS. THOMPSON: And asked and answered and object to the form and answer it if you can. If you can't, you can't.
THE WITNESS: Then we can proceed.
BY MR. OTTAWAY:
Q. You cannot answer it?
A. I answered it already.
MR. OTTAWAY: Okay. That's it. Let's go off the record just a second.
THE VIDEOGRAPHER: Time now is 11:21. We are going off the record.
(Recess - 11:21 a.m. - 11:23 a.m.)
THE VIDEOGRAPHER: Time now is 11:23. We are back on the record.
BY MR. OTTAWAY:
Q. Doctor, do you agree that pelvic pain and pain with sex can result from any pelvic floor surgery?
MS. THOMPSON: Object to form.
THE WITNESS: So pelvic pain?

Page 60

And pain with sex can? So you cannot be more specific about the surgery?
So generally when we do surgery, we don't want any of those.
BY MR. OTTAWAY:
Q. I understand and I didn't suggest that you did.
A. Yeah.
Q. I merely ask if they can result from.
A. They shouldn't. If it happens, you wonder what went wrong.
Q. Do you consent your patients to that possibility before you perform surgery?
MS. THOMPSON: Object to form.
THE WITNESS: I consent my patients that when they have surgery, they can have any problem including, but not limited to, death.
BY MR. OTTAWAY:
Q. And do those problems include pelvic pain or discomfort with intercourse?
A. Yes, but then they would ask me about the surgery I'm doing and they would ask me

Page 61

personally how much problem I've had with doing that surgery, and I would give them a specific replies.
Q. Doctor, can those problems also occur without surgery as a result of, say, aging?
MS. THOMPSON: Object.
BY MR. OTTAWAY:
Q. Lack of hormones?
MS. THOMPSON: Object to form.
THE WITNESS: So can somebody have spontaneous pelvic pain because they are getting older?
BY MR. OTTAWAY:
Q. Is -- yes.
A. Everything is possible, but that would be very unusual.
Q. Okay. Are there comorbidities that can cause pelvic pain and discomfort during intercourse?
A. So could you refine that question?
Q. I'm not sure that I can.
A. So describe comorbidities associated with pelvic pain and discomfort with intercourse?
So when somebody has pelvic pain and

Page 62

pain with intercourse that affects their quality of life, their relationship with their spouse, their children, it probably decreases their economic productivity.

Q. Strike that as nonresponsive.

MS. THOMPSON: I think the question is comorbidities is --

MR. OTTAWAY: Again, you don't have to argue about it, counsel.

MS. THOMPSON: -- is not the right word to use. He answered the question using the word "comorbidities" that can cause pelvic pain and discomfort.

MR. OTTAWAY: Actually, he didn't answer the question. He described the difficulties, but I move to strike.

MS. THOMPSON: Okay. Okay.

MR. OTTAWAY: And the judge can work all that out later.

MS. THOMPSON: I'll ask.

MR. OTTAWAY: We're not going to work it out here today.

THE WITNESS: So, again, yeah. If you could give me a more specific

Page 63

question. So the way --

BY MR. OTTAWAY:

Q. Do people have complaints of pelvic pain and discomfort during sex without ever having any kind of surgery?

A. So you're asking me what are the other causes of pain with intercourse and pelvic pain --

Q. Yes.

A. -- if somebody did not have surgery?

Q. Yeah.

A. Is that correct?

Q. I'm asking you if people can have complaints of those types and never had surgery.

A. True.

Q. Never had surgery involving mesh of any type?

A. True. Depends on the kind of pain that they have.

Q. And when you look at a reason that someone has those difficulties, do you consider their presurgical complaints to be important in that analysis?

A. Well, it depends on the --

Page 64

MS. THOMPSON: Object to form.

THE WITNESS: Yeah. It depends on the location of the pain and where the pain is. So pelvic pain is a very global term that you are using. It means anywhere in the pelvis.

Certainly if somebody had mesh-type pain, that can become bigger and become pelvic pain but, you know, you could also have pain that started from the mesh.

BY MR. OTTAWAY:

Q. Well, I think my question was, Doctor: Do you consider presurgical complaints of pelvic pain and discomfort with intercourse when you try to determine whether a surgery of any type is a contributing factor to them?

A. So if I saw a patient who has pain, yes, I would ask them what kind of pain they have before surgery.

Q. And would that be an important finding for you in determining a cause?

A. Depends on where their pain is and where it's coming from. So, for example, the patient who has endometriosis pain and they have

Page 65

stress urinary incontinence and they have mesh-related pain as a consequence in the future, they would have two sources of pain.

Q. When you say vaginal agenesis, a-g-e-n-e-s-i-s, what do you mean?

A. Can I see where the word is?

Q. Page 2 of your report.

A. Can I have the report?

Q. You can. It's right there in front of you, Doctor. Yes, of course. You're free to refer to it whenever you want.

A. So where are you looking at?

Q. Bottom of page 2.

A. Oh, agenesis.

Q. I've spelled it because I was sure I would mispronounce it.

A. Sorry about that.

Q. (Laugh). Don't be sorry I mispronounce something. I'm the one that has to be sorry about that.

I asked you what you mean when you say it, though.

A. When -- when the body is forming between three, two, four weeks of gestation to

Page 66

somewhere about five months of gestation, you basically have the Müllerian components of mesonephric duct and paramesonephric duct that have to migrate inside the body to form the uterus and form the vagina.

And when those migrations of embryologic tissue doesn't occur as programmed, then you may have anomalies in the vaginal tract. One of them being vaginal agenesis meaning the vagina just doesn't form. So externally the patient would look normal, but they would not have a formed vagina.

Q. All right. Thank you. I just wondered about that.

A. Thanks.

Q. Let's go to page 15. The very first sentence. You see it there?

A. (Nods head).

Q. You've cited a number of references for that sentence.

A. Which one?

Q. Footnote 3.

A. Which sentence?

Q. Very first sentence, page 15.

Page 67

A. "Includes vaginal discharge"?

Q. Yes. Well, the whole sentence, not just...

A. Page 15. "Includes vaginal discharge and bleeding." Is that the sentence?

Q. I sure hope we got the same report here. Are you on page 15?

A. I am.

Q. The very first sentence.

MS. THOMPSON: Oh.

THE WITNESS: "The most common complications."

BY MR. OTTAWAY:

Q. Yes, there you go. Got it?

A. Yeah.

Q. Okay. You see Footnote 3 there?

A. Okay.

Q. And then there is a string of citations --

A. Uh-huh.

Q. -- for your opinion; correct?

A. Sure.

Q. All right. When, in your opinion, did the medical literature begin to support these

Page 68

complications as being associated with mesh procedures?

MS. THOMPSON: Object to form.

THE WITNESS: So when does the medical literature support that? So what was the question again?

BY MR. OTTAWAY:

Q. Well, Doctor, I'm not trying to be tricky.

A. Yeah, I'm just not understanding the question.

Q. You say the most common complications associated with mesh procedures --

A. Uh-huh.

Q. -- as in our experience and as reported in the medical literature are pain, dyspareunia -- which means painful intercourse; correct?

A. Uh-huh.

Q. Yes?

A. True.

Q. Erosion and de novo urinary tract systems?

A. Uh-huh. True.

Page 69

Q. I want to know when those problems were reported in the medical literature.

A. Well, these papers, you mean when they were published? 2014 and 2015 and 2011.

Q. Okay. So 2011?

A. 2012. Yeah, there's a string of them.

Q. Okay. And would you agree with me that by those dates, it was known in the medical literature that these complications, in your phrase, were associated with mesh procedures?

MS. THOMPSON: Object to form.

THE WITNESS: These are some of the references I took. Doesn't mean there are -- there are not more of them --

BY MR. OTTAWAY:

Q. Oh.

A. -- or older ones or newer ones.

Q. In fact, there are references to these potential complications in literature older than 2011; correct?

A. True.

Q. Okay. So these were known to the medical community, people in your profession, by

Page 70

a review of the medical literature prior to 2011; correct?
A. True.
Q. Doctor, you discuss scarring.
Is scarring a potential with any surgery?
A. True.
Q. You learned that in medical school?
A. Probably.
Q. In the TOPAS product you discussed, is the mesh designed to have tissue in-growth?
A. Is the mesh designed to have tissue in-growth, question mark.
I think that's just a consequence of placing mesh in any space.
Q. And you understand that scar tissue may result from that?
A. That's the body response.
Q. You understand that if the body reacts to polypropylene, it may react to that device?
A. So there is inflammation and scarring of the tissue. True.
Q. Okay. And doctors have known that

Page 71

for a long time, haven't they?
MS. THOMPSON: Object to form.
THE WITNESS: That polypropylene causes scarring and inflammation? Or what is "that"? Could you question -- repeat your question?
BY MR. OTTAWAY:
Q. Doctors have known for a long time that scar tissue can result from surgery; correct?
A. Our body goes through a cycle of healing, some of which includes scarification.
Q. Okay.
A. That's body's first response to heal.
Q. And you teach your medical students that if you implant a device, whether it's TOPAS or any other device, you can have a reaction to that device; correct?
MS. THOMPSON: Object to form.
THE WITNESS: True.
BY MR. OTTAWAY:
Q. And these are things that are known and reported in the literature and have been

Page 72

since before 2011; correct?
MS. THOMPSON: Object to form.
THE WITNESS: What things? The scarring?
BY MR. OTTAWAY:
Q. Scarring, foreign body reaction.
MS. THOMPSON: Object to form.
THE WITNESS: Yes, the body forms a scar.
BY MR. OTTAWAY:
Q. I need to learn a little bit about EVUS, E-V-U-S. Is that how you pronounce that acronym?
A. Yes. What page are you on?
Q. It's all through there, Doctor. You can pick almost any page you want.
You know what I'm talking about when I mention EVUS; correct?
A. True. Even though now we just don't -- pretty much just say US, which is ultrasound.
Q. Okay. What does EVUS stand for?
A. EVUS is endovaginal ultrasound.
Q. And this is a technique that you

Page 73

rely on?
A. Well, when we do ultrasound, we -- when we say "EVUS," we are really talking about multicompartmental ultrasound, which includes transperineal and transvaginal probably.
Q. And how long has EVUS been available?
A. Oh. Well, endovaginal ultrasound has been performed for years. I don't know. Probably goes back to 1950s.
Q. Okay. How about three-dimensional endovaginal ultrasound?
A. Probably that goes back to 15 years at least.
Q. Okay. And have the organizations we've previously discussed, AUGS or ACOG, adopted three --
(Cell phone interruption.)
Do you need to take that? Doctor, let's go off the record if you need to.
A. Not me.
THE VIDEOGRAPHER: Time now is 11:40. We are going off the record.
(Recess - 11:40 a.m.

Page 74

- 11:40 a.m.)
THE VIDEOGRAPHER: Time now is 11:40. We are back on the record.
BY MR. OTTAWAY:
Q. Page 17 of your report.
A. Sure.
Q. I'll just read a sentence, and then I want to ask you a question about it.
"Multiple publications have determined that three-dimensional endovaginal ultrasound is a reliable, reproducible, and well-accepted method for assessing pelvic floor conditions, including mesh complications."
Have I read that correctly?
A. True.
Q. Okay. Now, my question is: Have AUGS or ACOG been among the organizations that have determined that three-dimensional endovaginal ultrasound is a reliable, reproductive, and well-accepted method for accessing -- assessing pelvic floor conditions, including mesh complications?
MS. THOMPSON: Object to form.
THE WITNESS: I think to answer

Page 75

your question, International Urogyne Association has determined that ultrasound is the gold standard for endosphincter imaging and so on and so forth.
BY MR. OTTAWAY:
Q. Okay. My question was AUGS and ACOG. You mentioned the international society.
A. Uh-huh.
Q. How about AUGS and ACOG? How about the answer to my question?
MS. THOMPSON: Object to form.
THE WITNESS: Have they released a statement saying that? That what? That exactly the sentence that we said?
The sentence is saying that there are a lot of publications supporting its use.
BY MR. OTTAWAY:
Q. And my question is: Are AUGS and ACOG among them?
MS. THOMPSON: Object to form.
THE WITNESS: I have to review it.
BY MR. OTTAWAY:

Page 76

Q. You can't tell me the answer right now?
MS. THOMPSON: Well --
THE WITNESS: I know you --
MS. THOMPSON: -- AUGS and ACOG aren't publications.
MR. OTTAWAY: I'm just asking if they got publications or positions.
MS. THOMPSON: If you can't answer the question, you don't answer.
THE WITNESS: I know IUGA has released a statement. I have to review the AUGS and ACOG, but they traditionally do not release those kind of statements.
BY MR. OTTAWAY:
Q. Okay. You mentioned the international society referring to ultrasound as the gold standard?
A. Yeah.
Q. Is that the same phrase that the organizations I just mentioned, AUGS and ACOG, use to describe mid-urethral slings?
A. So --
MS. THOMPSON: Object to form.

Page 77

THE WITNESS: So -- so I'm just trying to wrap my brain around the question you have.
BY MR. OTTAWAY:
Q. Well, I'm glad I asked one that required you to wrap your brain around it.
A. I don't understand it. So you -- we were talking about ultrasound and IUGA, and then you said something.
Q. It's really not that difficult, Doctor.
A. Okay.
Q. You told me that an organization and you cited it -- the international society -- referred to this ultrasound as the gold standard; correct? Remember saying that?
A. True.
Q. Okay. Have you heard that phrase, that same phrase "gold standard" applied for the use of mid-urethral slings to treat stress urinary incontinence?
A. By ACOG and AUGS?
Q. Yes.
A. I cannot recall.

Page 78

Q. I think we've covered this before, but I just want to make sure.
Exhibit 2 there. Are those the only Ethicon documents upon which you rely to support the opinion at page 19 of your report?
A. Go ahead.
Q. It starts out "I reviewed Ethicon documents."
Are those the only Ethicon documents you reviewed to support that part of your opinion?
A. I believe so.
Q. All right. When you say "mesh contraction," what do you mean?
A. Mesh being smaller than it was implanted.
Q. Okay. And when does the literature first discuss that as a potential with polypropylene mesh?
A. Probably somewhere in 1950s, '60s with mesh for hernia repair.
Q. And mesh has been used -- polypropylene mesh has been used for years in surgical situations, whether it's sutures or

Page 79

woven mesh or medical devices such as mid-urethral slings? Is that a true statement?
A. It has been used for hernia repair and has had complications, and people have tried to move away from it into other type of products.
Q. But that's been known, this contraction issue you discuss, for many years in the medical community to people who practice in the profession that you do?
MS. THOMPSON: Object to form.
THE WITNESS: So do people know that mesh contracts?
BY MR. OTTAWAY:
Q. Yes.
A. I think they are told that it doesn't, and it depends on how much of the literature they are reading and how critically they are looking at the literature.
Q. Okay. Someone who looks at the literature would be able to find support for that proposition?
A. That mesh contracts?
Q. Yes.
A. Yes.

Page 80

Q. Okay. If you go to page 5 of your report, Doctor.
A. Go ahead.
MR. OTTAWAY: We're going to get into some of your opinions.
How long have we been going, Ms. Reporter?
THE VIDEOGRAPHER: 43 minutes.
MR. OTTAWAY: 43. Let's go ahead and take another break. I told you we'd break about every 45 minutes, and this is a good time to do so.
THE WITNESS: Okay. Has it been 45 minutes?
MR. OTTAWAY: It has. Have you been having fun and time flies when you're having fun?
THE WITNESS: Yeah, it's just -- that's fine. We can take like five minutes; right?
THE VIDEOGRAPHER: Time now is 11:49. We are going off the record.
(Recess - 11:49 a.m.. - 12:03 p.m.)

Page 81

THE VIDEOGRAPHER: Time now is 12:03. We are back on the record. This is the beginning of disk No. 2.
BY MR. OTTAWAY:
Q. Dr. Shobeiri, I had referred you when we broke to page 5 of your report, which is titled "Summary of Opinions."
A. Yes, sir.
Q. Have you had a chance to review that while we were on break?
A. No. I was actually looking at IFU.
Q. Okay. Well, I take it you're familiar with these opinions?
A. Yes.
Q. And I want to ask you about them --
A. Uh-huh.
Q. -- one at a time.
A. Sure.
Q. Tell me about opinion number 1. What is your opinion and upon what do you base it?
A. Mesh complications are unlike those seen with the other pelvic surgery in terms of onset, frequency, severity, character,

Page 82

responsiveness to treatment.
So in terms of TVT-O, the mesh arms are going through a space that generally obstetrician/gynecologists were not familiar with. So the kind of problems that occurred in terms of dealing with those problems, really understanding the frequency, the severity, the character of them, how to respond to, are very difficult.
Q. Okay. And --
A. So traditional pelvic surgery, complications that OB-GYNs were used to were, you know, urethral injury or bladder injury or those kind of things. So these are very unique type of problems.
Q. Okay. Tell me exactly what you refer to when you say "complications."
MS. THOMPSON: Object to form.
THE WITNESS: Complications in terms of TVT-O, we are talking about the spaces traversing the response of local tissue to mesh in that area, the proximity of the sling arm to nerve vasculature that, you know, were just unfamiliar territory.

Page 83

BY MR. OTTAWAY:
Q. I'm really trying to understand, Doctor, but you've kind of skipped down to what I think would be number 6 or 7 or one of the others.
Does this refer to TVT-O specifically or mesh products in general?
A. I think in terms --
Q. Number 1.
A. Yeah. In terms of this report, we are talking about TVT-O.
Q. Okay. And when you say "mesh" up here in number 1, you mean TVT-O?
A. I think we are talking -- saying TVT-O mesh complications.
Q. Okay. Thank you for that.
And why do you say they differ in severity, frequency, and responsiveness to treatment? I want to know the basis of those opinions.
A. Uh-huh. So because the mesh arms -- and all of these opinions really melt into each other -- go through a space that OB-GYNs were not traditionally familiar with.

Page 84

Q. Are you talking about the --
A. Obturator space.
Q. -- obturator space?
A. Yeah.
Q. Okay.
A. So in terms of frequency, they didn't know how frequently that would occur. If it occurred, in terms of severity, they didn't know how severe it could be, what character to expect, and how to respond to it.
Q. Okay. And in your mind, is there a difference between the inside-out and outside-in technique for purposes of your criticism number 1?
A. Well, the TVT-O course is -- can be unreliable and -- and they do travel tracts that are different.
Q. Okay. Tell me how that is. Describe to me the different tracts, if you will, and why that makes a difference, if it does, to your opinion.
A. Uh-huh. So, for example, I told you with the TOTs at one point and the problem with that was that, you know, you -- you had the

Page 85

ability to hug the bone as you were coming around, but then the problem it posed was that it would be too close either to the vaginal skin or perforate the skin. So you have erosion problem, and that was the problem that was recognized.
And potentially TVT-O going from inside-out would alleviate that problem, but then the trajectory of the needle going the other way into the thigh to the mesh to a separate area.
Q. Okay. And what did that have to do with the onset frequency, severity, character of the injury, or responsiveness to treatment?
A. Well, you are putting the mesh close to the anterior and posterior branches of the obturator nerve. So you're -- you're operating in a space that people are not used to, and you're not really foreseeing that those nerves are there and what the body response would be to it in terms of pain. So that creates unique problems.
Q. Okay. And what -- how do those problems manifest?
A. Leg pain, groin pain, you know, and the company thought that they would go away

Page 86

within the first 24 hours, 48 hours but, you know, when they persist, they don't go away even if after you try to remove the mesh.

Q. Okay. Have you reviewed peer-reviewed literature which suggests that this leg and groin pain is transitory?

MS. THOMPSON: Object to form.

BY MR. OTTAWAY:

Q. You can answer, Doctor.

A. Have I reviewed? So the -- yeah, there is the data in the literature that as high as like 25 percent of patients can have this pain to begin with, and it sort of settles down to somewhere about 3 percent that is persistent.

Q. Okay. Your second opinion -- have you finished on number 1?

A. Sure.

Q. Okay. Number 2. Three-dimensional endovaginal ultrasound is a reliable, reproducible, etc.

Tell me what your opinion is there and how it relates to TVT-O.

A. Sure. So pelvic floor ultrasound has been used for many, many years and used to

Page 87

assess all sorts of pelvic floor condition from birth-related trauma to prolapse to incontinence to vaginal masses and cysts and mesh and that's about it.

Q. Okay. And how does that relate to TVT-O specifically? If it does?

A. Well, the ultrasound is -- shows you what's under the skin. So if you want to see the -- where the TVT-O is, how it's traveling, how -- how it's behaving inside the body, you can see it.

Q. All right. And that kind of bleeds into number 3, as I understand your testimony.

So tell me how this ultrasound reveals important things, in your opinion, about trends.

A. So, again, ultrasound just shows you what's under the skin. You -- you do the ultrasound and you see the sling, and you can document where it's going and where its location is.

Q. And regarding TVT-O --

A. Uh-huh.

Q. -- specifically, take me down

Page 88

through your opinions and tell me what this ultrasound tells you about that that's important in forming your opinion.

A. Sure. Ultrasound would show me where the TVT-O goes, whether it's lying down flat, whether it's caught at, whether it's mid-urethral, whether it's placed too high close to the bladder. It would show me really the -- granted that if all the physicians are educated similarly on how to perform this procedure, does the product actually end up being where it's intended to be. So --

Q. And what have you found in that regard?

A. The -- again, it depends on the patient. You can see whether it's flat, it's folding, whether it's prominent and its touching the vaginal skin, whether it's lopsided.

So, again, when you read the operative reports from physicians saying that they -- they did the procedure exactly as they were taught, and then you do the ultrasound and you see that sling is traveling in really places that you wouldn't expect, that would give you --

Page 89

give us an insight into the pathophysiology of the patient's pain.

Q. And, Doctor, have you reduced these discussions you're having with me now about this -- these findings on ultrasound to some sort of paper?

A. We do have --

MS. THOMPSON: Object to form.

THE WITNESS: -- in the references, yes, there are papers that we have published or they're out there. Yeah.

BY MR. OTTAWAY:

Q. And the reason I ask is because I looked at your resumé and came up with a few, and I wondered whether these had been reduced to writing. They're listed under your submissions.

A. If they say "accepted" or "in publication," then those are the ones you want to look at.

Q. Right. There are several here listed "In progress." 108, 109, and 111.

A. I'm wondering if you have the old CV or the new CV.

Q. I wouldn't have a clue, Doctor. I

Page 90

have what --
A. Does it have --
Q. -- counsel provided me.
A. Does it on top say updated what date?
Q. I can answer that question, but it's at the bottom.
A. I'm sorry.
Q. And it says it was updated February 1, 2016 at 8:01 a.m.
A. So that means it's pretty recent.
Q. Okay. So my question, again, is: There are three articles or three works here that are attributed to you and Mr. Javadian?
A. Javadian, yeah.
Q. Javadian. I want to pronounce it correctly.
The first being "Ultrasonic Predictors of Mesh Complications." It says "In progress."
A. Okay.
Q. The next one is "Transobturator Tape Syndrome: Ultrasonic Predictors of Pain." It says "in progress."

Page 91

A. In progress.
Q. And the third is "Public Health Impact of Vaginal Mesh Complications on Women's Health: In progress."
A. I know that one has been submitted.
Q. Okay. Submitted to whom?
A. Probably American Journal of OB-GYN.
Q. Okay. And has it been accepted for publication?
A. I'm not sure.
Q. So it exists in some form we can see that's been submitted to a journal?
MS. THOMPSON: Object to form.
And you can answer the question but -- but --
THE WITNESS: The one --
MS. THOMPSON: -- but subject to whatever the standard is for submitted publications that have not yet been published.
THE WITNESS: Yeah. We can -- we can give you the Public Health impact paper probably. I will check with my counsel and see how that goes.

Page 92

BY MR. OTTAWAY:
Q. Okay. How about -- how about the other two I mentioned, 108 and 109?
A. The other two, they have probably been submitted in abstract form. I have to check into it.
Q. Okay. And if they've been submitted in abstract form, can they be provided to us as well?
A. Yeah, if they are. I can -- I cannot recall whether I have a confirmation of submission yet. But if they are not submitted yet, they will be submitted.
Q. Okay. I'm sorry. We were talking about mesh findings on ultrasound and we were on number 4 of your opinion, Doctor.
A. Great.
Q. I take it this mesh again refers to TVT-O?
A. Yes.
Q. Okay. It says "deformation."
What do you mean when you say "deformation"?
A. Deformation? Well, it has been --

Page 93

it's clarified in parens. It says "flat, folding, prominence, or convoluted."
Q. And then it says "etc." I want to know what "etc." is.
A. We looked at different sling common -- common sort of sling presentations on ultrasound. And those are the four common ones, but there were probably a few that do not fit in those categories. And those would be maybe somebody who had their sling removed, and they had a residual piece of sling mesh left in there or --
Q. Well, I noticed it goes on and talks about residual mesh.
A. Yes. So that's probably one of the examples.
Q. Do you know anything else that fits into the "etc." you can come up with today?
A. So "etc." would be somebody who has sling, you know, complication, TVT-O complication. Maybe they have a hematoma in the area. Or --
Q. Okay. I'm sorry.
A. -- maybe they -- go ahead.

Page 94

Q. No, you finish your answer.
A. See if they have blood collection in the area or maybe there's an abscess or such. That would be "etc."
Q. And are these findings limited to TVT-O, or did they include all mid-urethral slings?
MS. THOMPSON: Object to form.
THE WITNESS: These would be transobturator slings.
BY MR. OTTAWAY:
Q. Okay. And where would I find this findings or these findings published?
A. Well, I think these are the ones that you were asking about about submission. So when we submit them, they would be available in abstract form.
Q. Okay. But you're not aware of any current publication containing these findings?
MS. THOMPSON: Object to form.
THE WITNESS: They do -- they could be in different publications, and they could be in some of our other publications that we have.

Page 95

BY MR. OTTAWAY:
Q. Okay. Can you cite me to any as we sit here?
A. So in -- there's a paper by Denson, D-e-n-s-o-n. So that probably would point you to some of those patterns.
Q. Are all of those contained in your Exhibit B? When I say "Exhibit B" I mean Exhibit B to your report, which is your reliance materials.
MS. THOMPSON: Object to form.
THE WITNESS: Probably that paper is in there.
BY MR. OTTAWAY:
Q. The next one is mesh contraction defined as shrinkage or reduction in size. You list it as a well-known occurrence.
A. Uh-huh.
Q. When you say "well-known," does that mean reported in the literature?
A. It's reported in the literature. Sure. Yep.
Q. Okay. And that literature is available to all physicians in your specialty?

Page 96

A. Sure.
Q. And do you teach your medical students that that is an important part of their education, when they're deciding whether to use a device or not, to consult the medical literature about that device?
A. So am I teaching my medical students that mesh contraction is important?
Q. No. What I asked you was: Do you teach your medical students that reference to peer-reviewed literature is an important part of their education when they go about trying to decide whether to use a medical device or any medical procedure?
MS. THOMPSON: Object to form.
THE WITNESS: We teach our students and residents evidence-based medicine.
BY MR. OTTAWAY:
Q. Which means? Which means?
A. Which means we have the literature, case reports, and learn to read it just because within writing doesn't mean it's, you have to take it. You need to read it critically and you

Page 97

need to investigate and look at the evidence.
Q. Now, number 6, I think this is where you were telling me about what you referred to as the wings; am I right?
A. Sure.
Q. Okay. Tell me about that, please, if we didn't get it all already.
A. Sure. The lateral portion of the Gynecare TVT-O mesh devices are difficult, if not impossible, to remove, even with the aid of advanced imaging and the surgical skill and result in seeing of comorbidity for patients.
So it goes to what we talked about where the sling arms are going into a space that is really unfamiliar to the general OB-GYNs or general urologists who are doing these surgeries.
And when we go to remove the mesh because of the pain, nerve entrapment, etc., as the sling arm advances and goes behind the tissue pubic rami it pretty much is turning behind the wall, so to speak, and it's just hard to follow.
Q. Anything else you need tell me about number 6?
A. Pardon me?

Page 98

Q. Anything else you need to tell me about opinion number 6?
A. Well, the last sentence that it says results in significant morbidity for the patient. Once you have scarring around the nerve causing the pain, a lot of times even if when you go and remove the sling, the scarring is still there and the pain may not be reduced, depending on when the original sling was placed.
Q. And do you reference specific literature to support that opinion?
MS. THOMPSON: Object to form.
THE WITNESS: Am I citing a specific reference for relating to that? I think it is in my references. We can look it up.
BY MR. OTTAWAY:
Q. We'll do that at the next break, Doctor, and you can tell me. I don't want to take your time here.
But if you do reference a specific piece of literature to support number 6, I would appreciate you finding it for me on the next break, okay?

Page 99

A. Do I have any of the papers with me?
Oh, no, I need the papers. So those are just the references.
Maybe, maybe not. I have to look at them.
Q. Okay. And if you find one, will you advise --
A. Sure.
Q. -- Counsel here so she can advise us?
A. Sure.
Q. Okay. Number 7. TVT-O is associated with an unacceptably high rate of chronic pain.
Tell me about that. What do you rely on to support that opinion?
A. Sure. So, again, you get to the fact that you're operating in a space that causes the kind of pain that is hard to get rid of --
Q. Okay.
A. -- and that's unacceptable.
Q. Okay. Now, are we talking about a particular kind of pain here?
A. We are talking about groin pain and

Page 100

the leg pain that the patients experience.
Q. So it's groin and leg pain.
And do you have in your mind what an acceptable rate of pain would be?
MS. THOMPSON: Object to form.
BY MR. OTTAWAY:
Q. You say this is "unacceptably high."
Do you have an opinion about what would be acceptable, in your opinion?
A. Acceptable rate --
MS. THOMPSON: Object to form.
THE WITNESS: -- of chronic pain for me would be none.
BY MR. OTTAWAY:
Q. Okay. So anything above zero is an unacceptably high rate of chronic pain to you?
MS. THOMPSON: Object to form.
THE WITNESS: I don't want my patients to have any chronic pain.
BY MR. OTTAWAY:
Q. Okay. I'm just asking what your opinion is here, Doctor.
Was my statement correct?
A. My opinion is that if the patient

Page 101

walked into your office without chronic pain and they're to take care -- they're to have their urinary incontinence taken care of, they should not walk away with chronic debilitating pain.
Q. Is --
A. So it's unacceptable.
Q. Okay. Any level? Anything above zero percent?
A. If my patient walked into my office and they had that surgery done, and they came to me and they said they are having this pain, I -- I would take it very seriously.
And likely I would remove that sling very quickly before the scarring sets in and she has chronic pain.
Q. Okay. Number 9.
By the way, I'll tell you. We looked at your reference material. We didn't see the paper listed by Denson.
A. Pardon me?
Q. We didn't list -- see a paper listed by the author you referenced.
A. Oh, okay. Well, you can -- it's probably -- I'll find it for you. That's fine.

Page 102

Q. Okay. 9 and 10 kind of are related to each other. Tell me about those.
A. So this is the same sort of thing that we talked about.
If a patient walks into my office, not having had this pain but purely for treatment of urinary incontinence, and then they wake up after the procedure, they have pain that persists, given what I told you about the course of unpredictive -- unpredictable course of the slings that has been shown both in the literature and can also be -- be seen by ultrasound, it's safe to conclude that they're having a device-related complication.
Q. Again, Doctor, I'm going to ask you if you're referencing there any specific literature upon which you rely to support your opinion.
A. The -- I believe we have the references in the list of references, I believe.
Q. Okay. So everything I would find in your list of reliance materials in Exhibit B to your report?
A. Pardon me?

Page 103

Q. Everything you rely on is contained in Exhibit B to your report, which is your reliance materials?
MS. THOMPSON: Do you have Exhibit B that he could --
MS. FISCHER: Go off the record, please.
MS. THOMPSON: You don't have to go off the record to mark an exhibit.
MS. FISCHER: Are you refusing my request to go off the record?
MS. THOMPSON: Well, we're taking a lot of breaks.
MS. FISCHER: Two. We've taken two. Are you refusing my request to go off the record?
MS. THOMPSON: No, I'm not refusing. I'm just suggesting if you're going to do something that takes 10 seconds, it's probably more efficient to stay on the record.
MS. FISCHER: Are we off the record or not?
MS. THOMPSON: Yeah. Go off the

Page 104

record.
THE VIDEOGRAPHER: Time now is 12:32. We are going off the record.
(Recess - 12:32 p.m.
- 12:32 p.m.)
THE VIDEOGRAPHER: Time now is 12:32. We are back on the record.
(Document marked, for identification purposes, as Defendant's Exhibit No. 3.)
BY MR. OTTAWAY:
Q. Doctor, we are back on the record and you've been handed an exhibit here, which is a part of your report labeled "Reliance Materials."
Can you go through there and reference, if you can, the specific support for the opinions we just discussed.
MS. THOMPSON: Object to form.
Well, answer that question however you want.
THE WITNESS: So -- so what you a handed me is a list of publications, you know, that we have coded and it's just a

Page 105

list of it. So what I require right now is the actual articles for me to go through and tell you where they are.
BY MR. OTTAWAY:
Q. Doctor, they didn't give them to us and, I mean, I guess they're available.
But do you have anything in your mind right now, any specific article you're referencing?
MS. THOMPSON: And -- and you also have to which opinion you're referring to.
MR. OTTAWAY: The same one we were just discussing, counsel. I haven't moved on.
MS. THOMPSON: Okay. Which one are we on?
MR. OTTAWAY: I'm sorry. Let's go back. I think it was 8 and 9.
THE WITNESS: 9 and 10.
MR. OTTAWAY: 9 and 10. See, I was pretty close. The doctor knew all the time.
MS. THOMPSON: Okay. Numbers 9

Page 106

and 10.
THE WITNESS: So there are a lot of articles supporting this. I have to see the actual articles to put it out for you.
BY MR. OTTAWAY:
Q. Okay. So you're not able to tell me just looking at the --
A. Yeah. They --
Q. -- exhibit I handed you?
A. They are a lot of articles and there are a lot of them that each of them looks at a different point, and I'll be happy to give you that information if I have the actual papers.
Q. Okay. Just keep going there, Doctor, and I want to take all the other opinions and ask you the same kind of thing.
Do you have any particular support you're relying on for them, or is this just, again, contained somewhere in your reliance materials?
A. For the what question?
Q. The rest of them, 10 on.
A. Yeah, I think they're all in the references that we have given you.

Page 107

Q. Okay. You have an opinion, Doctor, that the TVT-O is defective in design.
Exactly what defects in design do you reference?
A. Well, one thing we had talked about earlier is just the weave of the mesh, where the opening surgeon in the removal of the sheet, the sling frays and so cords and so that would change the properties of the mesh.
Q. Okay. Is that a -- is that a function of it being made out of polypropylene?
A. It's a function of design.
Q. Okay. Tell me the design function that it results from. Tell me what specifically about the design you're critical of.
A. Well, the fact that it's coils. It's ropes. It doesn't stay flat. The way the fact that it has edges that fray, you know. Those are the design flaws.
Q. Okay. Does the -- is this a common characteristic of all transobturator slings, both inside-out and outside-in?
MS. THOMPSON: Object to form.
THE WITNESS: So you're asking if

Page 108

all of them do that?
BY MR. OTTAWAY:
Q. Yes.
A. No. I mean, we have seen slings that don't do that.
Q. Okay. Tell me who manufactured those slings.
A. Who manufactures the slings that don't roll?
Q. Yes.
A. Well, for example, the -- most of the TVT type slings that we look at, they don't roll. They sit straight.
Q. Well, no. My question was specifically limited to transobturator slings.
A. Well, the TVT-Os we have looked at, they roll and they cause problems. And I told you we don't use TOTs anymore.
Q. Okay. Well, have you done a study, though, of TOTs in the same way that you have looked at TVT-Os to determine whether they roll, fray, curl?
A. Uh-huh.
Q. Tell me what you found.

Page 109

A. Well, the -- I think that both TOTs and TVT-Os can behave the same to some degree. The -- the ones that I have looked at have been the TVT-O and the Bard product, and I know those ones roll and cause issues.
Q. Okay. Any others that you've looked at?
A. There are some others, but off the top of my head, I would say that we have looked at some Boston Scientific products that also do the same thing. Their transobturators. So those are the three I can think of.
Q. So TVT-O is not unique in that regard?
MS. THOMPSON: Object to form.
THE WITNESS: The TVT-O probably is not unique in that regard, and but we are not using TOTs or TVT-Os.
BY MR. OTTAWAY:
Q. Doctor, if you can go to page 26 of your report. Middle paragraph starts "There are." Are you with me?
A. Sure.
Q. Okay. Tell me what in your opinion

Page 110

would have provided a safer alternative.
A. Well, in our practice, we are basically using the retropubic devices. We're using the TVT type devices.
Q. TVT devices manufactured by Ethicon?
A. Ethicon, Boston Scientific. You know, depends on what the hospital is providing us.
Q. So when you say "safer alternative," you mean retropubic TVT devices?
A. Yeah, that's the --
MS. THOMPSON: Object to form.
THE WITNESS: Those are the safer things.
MR. OTTAWAY: You have to let her get her objection out, Doctor.
Do you have an objection, counsel?
MS. THOMPSON: Object. Yeah, I object to form.
MR. OTTAWAY: Thank you.
BY MR. OTTAWAY:
Q. You may answer, Doctor. I'm sorry. If you can remember the question?

Page 111

A. Yeah. So we have -- we have moved to the more retropubic slings.
Q. Okay.
A. And we don't have TVT-Os on the shelf.
Q. Okay. And those include TVT devices made by Ethicon?
A. TVT devices by -- made by Ethicon.
Q. Okay. And when you say "safer alternative," that's what you mean?
MS. THOMPSON: Object to form.
THE WITNESS: That's what we are using now.
BY MR. OTTAWAY:
Q. Okay. Well, no. I'm asking you if that is the safer alternative you're referencing at page 26 of your report?
A. Yes. We are avoiding transobturator space and going to retropubic in appropriate patients.
Q. Okay. Is there medical literature, Doctor, of what you're aware in peer-reviewed journals which suggests that TVT devices and TVT-O devices are equivalent --

Page 112

MS. THOMPSON: Object to form.
BY MR. OTTAWAY:
Q. -- when it comes to safety and efficacy?
A. I'm aware of literature that say they are not equivalent.
Q. That wasn't my question again, Doctor.
If you can answer my question. I appreciate your answer, but can you answer my question?
A. Yes, there is literature saying that depending on the end point that they were looking at, those end points are equivalent.
Q. Okay. Thank you.
I noticed here at the last page of your report that you've already told us that you've stopped using TVT-O; correct?
A. Uh-huh. True.
Q. Are you aware of any academic center currently using TVT-O?
A. No, but that doesn't mean somebody out there is not using it.
Q. Have you made any effort to search

Page 113

and find out that information?
A. The people I have talked to and the people who are within my communication space are not using it, but it doesn't mean somebody out there is not.
Q. Okay. Even in an academic center?
A. True.
MR. OTTAWAY: How are we doing on time, Mr. Videographer?
THE VIDEOGRAPHER: Nine minutes to go.
MR. OTTAWAY: All right. Good. We'll finish out the nine minutes then.
BY MR. OTTAWAY:
Q. You have reviewed the IFU for TVT-O, Doctor?
A. Yes, I did.
Q. When you were performing TVT-O surgeries, had you reviewed it prior to doing them?
A. Yes.
Q. Did you also conduct your own review of literature to determine how other people were doing with the TVT-O or TOT device?

Page 114

A. I believe when we started using either of them, you know, we reviewed the available literature and we read the IFU.
Q. And that's why you say you practice evidence-based medicine; correct? Because that's something you do, review the literature before you start using a product?
MS. THOMPSON: Object to form.
THE WITNESS: We review the literature and read the IFU before we use the product.
BY MR. OTTAWAY:
Q. But you don't do one to the exclusion of the other; correct?
A. True.
Q. And you would expect other doctors sharing your specialty to do the same. True?
MS. THOMPSON: Object to form.
THE WITNESS: True.
BY MR. OTTAWAY:
Q. Now, you talk about adverse reactions that are listed in the IFU.
A. What page?
Q. I'm not trying to fool you here,

Page 115

Doctor. It's page 24 of your report if you want to go to it.
A. Okay.
Q. What adverse reactions are listed in the IFU?
A. So you want me to pull out the IFU?
Q. You're free to refer to it, Doctor. If you can't tell me without referring to it, of course you can.
A. Okay. (Reviewing document). So we have the warning and precautions and the adverse reactions section. What's your question about it?
Q. For example, is nerve pain mentioned?
A. Yes.
Q. We discussed scarring previously. As a physician, did you know scarring was a potential?
A. Yes.
Q. Did you know inflammatory or foreign body reaction was a potential?
A. With the TVT-O insertion?
Q. Yes.

Page 116

A. Well, the IFU says transitory local irritation and transitory foreign body response, which is what you expect the body to do when it's healing. So I really think that Ethicon minimized the extent of the problems that was occurring in the body.
Q. And were those problems noted in the literature to which you've referred?
A. So the question is?
Q. Well, you've talked about the IFU, and I know you disagree with the way it's worded.
A. Uh-huh.
Q. But regardless of how it's worded, was that information available in the peer-reviewed literature that you've referenced? You've said you've looked at peer-reviewed literature and the IFU.
MS. THOMPSON: Object to form of the question.
THE WITNESS: In terms of TVT-O?
BY MR. OTTAWAY:
Q. Yes.
MS. THOMPSON: I'm sorry. And misstates his previous testimony.

Page 117

BY MR. OTTAWAY:
Q. She has to get it all out, Doctor, and she's entitled to.
A. Yeah, in terms of the TVT-O being a new device, we went with the literature and IFU.
Q. Okay. Now, you talk about some of the adverse reactions on page 25 of your report?
A. Sure.
Q. Chronic pain. Is there a difference between chronic pain and chronic pain syndromes?
A. Yes.
Q. Okay. Tell me the difference.
A. Chronic pain is -- can be localized. Chronic pain syndrome can be a constellation of different systems.
Q. And which are you referring to here when you say "adverse reactions"?
A. Could be both.
Q. Okay. So it could be both. And are both noted and contained in the peer-reviewed literature? Supported by the peer-reviewed literature?
A. In terms of?
Q. TVT-O.

Page 118

A. TVT-O? Well, this comes from the IFU.
Q. Okay. How about chronic inflammation of tissue surrounding mesh?
A. What about it?
Q. Is -- are you able to find that in the peer-reviewed literature?
A. Yes.
Q. Scar plate formation, scar banding, contraction of mesh arms. Are you able to find that in the peer-reviewed literature?
A. Yes.
Q. Erosion of mesh and bladder into the bladder and recurrent exposure of mesh in the vagina. Are you able to find that in the literature?
A. Yes.
Q. By the way, are you able to find references to that with reference to just TVT meshes in the literature?
A. Which one?
Q. The four we just mentioned.
A. The mesh in the bladder?
Q. Yes.

Page 119

A. Yes. Yeah.
Q. So those four would be applicable to TVT-O and TVT; correct?
A. TVT-O. This is all about TVT-O.
Q. My question is, though: Are those same things noted in the literature for TVT mesh?
A. I have to look at the IFU.
Q. Okay. We are about run out of tape, Doctor. So we'll let the videographer take a break and you can take a break and we'll come back --
A. Okay.
Q. -- for our last session?
A. Great.
Q. Fair enough?
THE VIDEOGRAPHER: Time now is 12:50. We are going off the record.
(Recess - 12:50 p.m. - 1:01 p.m.)
THE VIDEOGRAPHER: The time now is 1:01. We are back on the record.
BY MR. OTTAWAY:
Q. Are you ready to go again, Doctor?
A. Yes, sir.
Q. All right. If you'll look at -- we were on page 25. If you'll flip over to page 26, first paragraph, and then we'll come back to 25 because I wanted to get at this.

Page 120

A. Sure.
Q. You reference in that paragraph:
"Information known to Ethicon from internal documents."
Do you see that?
A. First paragraph?
Q. Page 26.
A. (Reading document).
Q. Fourth sentence.
A. Oh, we're talking about the reference 26 or --
Q. Yes. Yes.
A. Okay. So what's the question?
Q. Okay. I want to know if this information known to Ethicon from internal documents is contained within the same documents that we showed you before in Exhibit 2 or if you're referring to something else there.
A. Cannot find the sentence you're talking. Let me just see.
Q. Starts with "These" in sentence or line 3.

Page 121

A. Page 26; right?
Q. Page 26, line 3. Starting -- the sentence starting "These." You'll notice something --
A. "These statements are misleading and inaccurate"; right? "Based on the information."
Q. Right. That's what I'm asking.
"Information known to Ethicon from internal documents."
Do you see that?
A. Yes.
Q. And are those internal documents the same ones we referred to earlier, or are you referring to other documents?
A. No, we are -- I'm -- I'm referring to the documents that we have here in one of the exhibits.
Q. Exhibit 2, I believe.
A. Exhibit 2 and also the references 26.
Q. Right. To the literature.
A. Yes.
Q. The only internal documents you're

Page 122

referring to are the ones we've previously talked about?
A. Yes.
Q. All right. Good. I'm sorry. I got diverted there.
A. No, no. I think we're one sentence off for some reason.
Q. No problem.
Doctor, back on page 25 now.
A. Yes.
Q. We were discussing -- one, two, three, four -- five bullet points down. We were on the fifth bullet point.
A. Yes.
Q. And as I understand your testimony, these are the kinds of adverse reactions, in quotes, that you can find in TVT-O, but they also can be found in other forms of mesh.
A. True.
Q. Okay. I'm sorry. I don't know what pudendal means, if I've even said that right.
So can you tell me, educate me in that regard?
A. Sure. Pudendal nerve is one of the

Page 123

nerves that supplies the clitoris, labia, perineal body, anus.
Q. Okay.
A. So that's...
Q. When you say "pudendal neuralgia or other neuropathies," is that something that's also a potential with any form of mesh?
A. We are talking in terms of TVT-O.
Q. Okay. I know -- I know that. Your report is about TVT-O.
I'm asking you if it also is an adverse reaction associated with other forms of mesh.
A. It can be associated with the other type of vaginal mesh kits, depending on how they placed -- how they are placed and what space they're utilizing.
Q. Okay.
A. So some of the mesh kits, they go to sacrospinous ligament, which is higher point in the nerve versus a transobturator area would be the lower point for some of the ranges.
Q. Nerve damage or nerve entrapment, scarification, and fibrotic bridging. Is that

Page 124

something that's a potential in any surgery?
A. Vaginal surgery you mean?
Q. Yes.
A. Well, the problem is that with the TVT-O type device, you are utilizing space that has the nerve in it. So that's the space that we normally don't go into. So this kind of nerve damage or neuropathy are not the kind of things that you would see with the normal vaginal surgery.
A lot of times when we tell our patients that they may have nerve problem when we are doing vaginal surgery for them, we are -- we may be talking about foot drop, leg drop because of the malposition of the leg, not really the nerve issues in the obturator canal or such. Not that with vaginal surgery they cannot happen, they're just very infrequent.
Q. Okay. So as I understand it, the TVT-O is unique in the regard that it goes through this obturator space; correct? The TVT-O or TOTs?
A. The devices that utilize that space.
Q. Okay. When you say "nerve damage or

Page 125

nerve entrapment," you're trying to limit that to the obturator space?
A. As it pertains to the TVT-O.
Q. But nerve damage and nerve entrapment or scarification is common to all surgery and all vaginal surgery, except just not in that area; is that right?
MS. THOMPSON: Object to scope. Object to form.
THE WITNESS: If you're operating close to the nerves, you can have nerve entrapment problems, just at the nerves that travel in that area. They are not really inside the vagina.
BY MR. OTTAWAY:
Q. Okay. The next one, pain with sex or sexual impairment. Is that a potential for any vaginal surgery?
MS. THOMPSON: Object to form.
THE WITNESS: The vaginal surgeries who could cause dyspareunia and sexual impairment a lot of times may be associated with narrowing of the vagina or inflammation in the space, and so they

Page 126

could cause pain and discomfort maybe in a different region.

BY MR. OTTAWAY:

Q. Okay. Is there something unique about TVT-O or TOT devices as it regards dyspareunia or sexual impairment?

A. Well, we are talking about the TVT-O, and what we talked about earlier was the fact that the TVT-O and the TOT type devices do curl up, you know, and then you asked me like what other complaints are making them.

So that from the -- the sling is going from one issue of PV grain white to the other issue of PV grain white. So...

Q. Okay. I want to make sure I understand this.

So is there -- because you mentioned -- we're going to talk about deformed curl rope, degraded, fragmented in your next opinion.

A. Yeah, they sort of run into each other.

Q. Yeah. I'm now referring to the bullet point above it.

Page 127

A. Yeah.

Q. Dyspareunia and sexual impairment. And my question is: Does that -- is that a potential for all vaginal surgeries?

A. Yeah, but then you put TVT and TVT-O together.

Q. Okay. And that is what you reference in the next bullet point is you're telling me because, in your opinion, the TVT-O or TOT devices tend to curl, rope, degrade based on your ultrasound examinations?

A. Yeah, but that's goes hand in hand with dyspareunia as well. Because -- because they're going from one side to the other, they sort of cause this bridge as well.

Q. Okay.

A. That can. So they behave differently from TV -- from TVT type devices.

Q. Okay. So in that one there's, in your mind, some difference between the TVT-O or TOT devices and standard TVT matter?

A. Well, they're anatomically in different spaces.

Q. Okay. Next bullet point.

Page 128

Encapsulation of mesh.

A. Yes.

Q. Okay. Is that unique to TVT-O or TOT devices?

A. No, it's all the mesh.

Q. Okay. Vaginal shortening or tightening stenosis. Is that unique to TVT-O or TOT devices, or is that something that occurs with vaginal surgeries or other meshes?

A. Yeah. If the -- any vaginal surgery could cause a stenosis and tightening and shortening, but this is different type of, again, problem with that bridging that we talked about.

Q. Okay. What is it that causes a different type of vaginal shortening, tightening or stenosis?

A. So with the stenosis, we are talking about the sling bridge, so to speak, that can be -- can cause issue in term of tightening that space versus if you're talking about a general vaginal surgery for something else.

Q. Okay. So would this be unique to TVT-O or TOT devices, or would it be something present with all mesh devices? Potential of all

Page 129

mesh devices?

A. We are -- here we are talking about TVT-O --

Q. Okay.

A. -- on this sentence.

Q. Infection. Is that unique to TVT-O or TOT devices or something you can see with all mesh?

A. Well, when things settle down, you know, you -- bladder infection can be one of the more frequent problems that you can have with TVT-Os.

And so can we see with the other type of mesh as well? You can see it with the other type of mesh as well, but it can be a different type of problem.

Q. And different in frequency, duration, severity?

A. So the -- so if you talk about mesh that's, for example, under the bladder and is coming through or working its way through, you know, you would have vaginal discharge and that type abnormal vaginal discharge would predispose you to -- to bladder infection.

Page 130

But at the same time, depending on how, whether it's a TVT or a mesh that is device inserted, you know, if there is any obstruction to the -- to the bladder also, you can get UTI. So they can melt into each other.

Q. Okay. What I'm hearing you saying is infection -- bladder infections can be present with all forms of mesh in addition to TVT-O.

Is that a correct statement? Is my statement correct?

A. Well, theoretically, you should not have it as much with mesh --

Q. Okay.

A. -- itself but more with the TVT-O.

Q. Okay. So that's a question of frequency, I guess?

A. Uh-huh. True.

Q. Both can do it, but in your judgment, TVT-O or TOT devices do it more often?

A. Repeat that question. Sorry about that. Do you want to?

Q. Well, yeah, it's all right.

A. Just make sure.

Q. I want to make sure we communicate

Page 131

so that you know that when you've answered my question, you've answered it with your opinion. Fair enough?

A. Well, I just want to make sure you understand what I said.

Q. Yes. Yeah. What I'm understanding you to say is: Infection can result from any mesh. Vaginal infection can result from any mesh.

A. Uh-huh.

Q. But in your opinion, urinary tract infections or bladder infections would be more common with TVT-O than with TVT mesh?

A. Yeah. The thing is that their mechanisms can be different, too.

Q. Okay. And that's --

A. That's what I was trying to stress.

Q. Yeah. Tell me about how their mechanisms can be different.

A. Well, what I was saying is that with the vaginal meshes that are placed, you know, if they're coming through and they're causing vaginal discharge, that would be the contributing factor. And that's true for TVT-O as well, but

Page 132

with the TVT-Os, if they're roping and rolling and they're a tube type and they're causing outflow problems to the bladder, they can also contribute to the bladder infection.

Q. Okay. And this roping and rolling you're discussing, is that, in your opinion, unique to TVT-O or TOT devices?

A. They are more often seen in those conditions.

Q. Okay. So not unique but more frequent. Fair?

A. The -- so we are talking about the roping and curling of the tissue?

Q. Yes.

A. Yeah. I mean, just because of the anatomy going from side to side, you see that.

Q. More frequently? I mean, it's a question of frequency? Not that it doesn't rope or roll in other meshes, it's just more frequent in?

A. Well, that's the condition that we have seen it in.

Q. Okay.

A. So...

Page 133

Q. I'm still not sure I got the answer there.

Do you see roping and rolling in other forms of mesh other than TVT-O and TOT?

A. That's where we have seen it. You know, I mean, if somebody puts a TVT and they are placed in a very tight manner, you know, I guess they could do that, but we don't see that as frequently versus with the TOT and TVT-O we do see that.

Q. So it is a question of frequency. That's what I'm trying to get at.

A. Yeah.

Q. Okay. De novo urinary symptoms. Is that something unique to TVT-O or TOT devices or something that is present in as a potential in vaginal surgery or mesh surgeries in general?

A. De novo urinary symptoms could be associated with both TVT-O and TVT type slings.

Q. Okay. Hyspareunia. What do you mean by hyspareunia, in quotes?

A. Again, because of the anatomy and the way that the sling would travel causing that bridge or scarring. As male tries to enter and

Page 134

have intercourse, they have pain.
Q. And is that something unique to TVT-O or TOT devices or can that be present with any TVT or mesh device?
A. The location would be different, depending on where you have the problem.
Q. Okay. Other than location?
A. So the presentation would be different for TVT-O device versus something that is placed deeper.
Q. Okay. Explain that to me, if you will. I want to understand.
A. So if you have a mesh under the bladder or over the rectum and it's working through, so the male can enter, but they would go halfway in, and they feel the mesh then and that would hurt them versus with the TVT-O is very much, you know, closer to the outside. So they would feel it. They cannot get very far.
Q. Okay. So it would be a question of location within the vagina then?
A. Yes.
Q. Thank you. I think I understand.
Is there any difference in the

Page 135

chemical composition of the polypropylene used in TVT-O and TVT mesh made by Ethicon that you're aware of?
MS. THOMPSON: Object to form.
The TVT-O compared to TVT or TVT-O and TVT compared to other mesh?
MR. OTTAWAY: I actually asked the question TVT-O and TVT manufactured by Ethicon, I believe.
THE WITNESS: So comparing TVT-O to --
MS. THOMPSON: Object to the form of the question.
THE WITNESS: -- TVT? They're both polypropylene.
BY MR. OTTAWAY:
Q. Okay. Are you aware of any differences in the chemical makeup of the two?
A. I think they are both polypropylene.
Q. Okay. And do you hold yourself out as an expert in biomaterials?
A. I know as much as it pertains to my work.
Q. Again, that wasn't my question.

Page 136

I asked you: Do you hold yourself out as an expert in biomaterials?
A. I'm not a biomaterial engineer.
Q. All right. Doctor, I'd like to ask you a question. If you want to refer to page 27, but it's referred to in several pages in your report.
What is your definition of a "community doctor"?
A. A community doctor? Where do I -- ah, I see here.
Community doctors are physicians who are working in the community. Probably physicians in nonacademic centers.
Q. And would they be gynecologists, urogynecologists?
A. Or -- or physicians in a non- -- non-tertiary type health centers.
Q. Would they be doctors who had access to the same reference material that you refer to in your Exhibit B to your report?
A. They would have access to it, but remember, for me I'm always reading articles continuously where those physicians may have

Page 137

certain societies they belong to or they would -- they may read one or the other journal.
Q. They can be doctors who are specializing in your specialty? Members of the same societies you're members of?
A. So are there community physicians who are urogynecologists? There are community urogynecologists as well.
Q. Now, the reason I ask that is because if you'll go to page 22?
A. Uh-huh.
Q. The second sentence on that page. That phrase "doctors in the community." Not community doctors, but "Doctors in the community --
A. Uh-huh.
Q. -- are often unaware of the risks of mesh."
You see that sentence?
A. I see that.
Q. Are you aware of any study that supports that opinion? It's not referenced to anything.
A. Well, I think we draw that from our

Page 138

studies where we were in Oklahoma at a tertiary care center, and we did a study where we saw 75 percent of patients who came to us with mesh complications with the sling complications.

They -- when we asked them who referred you to us, they said, you know, we -- I came here based on the referral from a friend or the church. And when we talked to the physicians, they were like OB-GYNs, know this was a problem. So it's actually documented in the literature how -- how these mesh complications may be seen, but most often they are told that maybe just give the patient estrogen and it would go away and it would end.

Q. Is estrogen an accepted form of therapy for some mesh complications?

A. You know, to the -- this type of mesh complications pertaining to TVT-O and such was something that I think crept up on the community, and a lot of times neither the community physicians nor us knew how to deal with them.

I mean, they came about and we were looking at ways to take care of the mesh problem,

Page 139

take care of the sling erosion problem nonsurgically. We did try estrogen and you may find references in the literature that it was advocated at one point, but it really fell out of favor because it just didn't work.

Q. Okay. There was an FDA paper you reference in your report issued in 2008.

A. Okay.

Q. Are you aware of that?

A. Yes.

Q. Did that FDA paper warn of the risks associated with mesh implantation?

A. Okay.

Q. Did it?

A. So what's the question?

Q. My question is: Did the FDA 2008 paper address the issue of --

A. Yeah, that was the FDA warning, warning of.

Q. -- risks of mesh?

A. They were -- they were alerting the community of -- of complications associated with the mesh and the sling that they were seeing.

Q. Okay. And did that go to doctors in

Page 140

the community?

A. It was pretty much a media blast. So whoever followed that probably learned about it quickly.

Q. And so your statement, "Unfortunately, doctors in the community are often not aware of the risks of mesh" would predate 2008?

MS. THOMPSON: Object to form.

THE WITNESS: Well, the study that we did was after that time. So doesn't seem like that filtrated into the community.

BY MR. OTTAWAY:

Q. And did you try to in your study -- and please refer me to the study you're referencing if it's in your materials there.

A. Sure.

Q. I'd like to know which study it is.

A. Uh-huh. It's the -- in the Oklahoma Medical Journal. I don't know what year it was, whether it's 2012 or '13. So...

Q. Okay. Did you make an effort in that study to determine whether this statement

Page 141

"Doctors in the community are not aware of the risks of mesh" was post or pre-2008, the implantation?

A. The study was done in 2012, '13, whenever it was published. So, I mean, you can draw a conclusion. If the warning came in 2008 and the study is published a few years later whether the physicians really got the message or not. I think that the -- you know, they -- they didn't refer us the patients and it doesn't seem like they were aware of the mesh problems that was going on. Whether -- yeah, go ahead.

Q. No, go ahead. Finish your answer, please.

A. So the study basically said about 75 percent of people were self-referred but not referred by the surgeon who did their surgery.

Q. And it's from that study you determined that "Doctors in the community are often not aware of the risks of mesh"?

A. That's -- that's the -- that's what we have observed.

Q. And did that study -- and again, you know, I know the study you're referencing on that

Page 142

one.
A. Uh-huh.
Q. Did that make any effort to determine whether the mesh was implanted pre or post the FDA 2008 advisory?
A. I see what you're asking.
So these are the patients who -- I mean, they could have had their mesh implanted before that as well. We didn't look at the exact date of implantation.
Q. Okay. Now, the last point I want to discuss with you -- because we're running out of time, and I want to take one very brief break for about 10 minutes left to make sure I got everything but -- is your opinion that TVT-O or TOT devices are more difficult to remove than other forms of TVT mesh.
Tell me about your opinion in that regard.
A. So it, again, goes to the matter of the space utilized to put those slings in. So if we had a TVT mesh, if you want to remove the whole thing, you could go retropubically, transvaginally and you could be pretty sure that

Page 143

you could remove 100 percent of it.
With the transobturator tape or the TVT-O, as we discussed, your arm of the sling goes lateral and behind the bone and disappears.
So most skilled surgeons -- again, has been a learning cycle for a lot of people who were not used to this area -- that's as far as they can go. So there is inevitably some mesh left in a patient where they can come back and say, I still have a problem there.
Q. Okay. How about in your experience, are you able to access and remove that mesh?
A. I -- I try to remove as much as I can, but I -- because you get into such a difficult space, most often that's where we will stop. You know, because then the idea of having to go through the groin to approach that space is -- it's very challenging as well.
Q. Now, having removed the mesh other than the mesh you've just described, what consequences would result from leaving just that portion of the mesh in?
A. Well, the patient is coming to you for pain, mesh complications problems, especially

Page 144

if it's pain issue, groin pain issue, leg pain that is radiating from the obturator territory. You know, the -- if that was really the thing that I was worried about, then, you know, I would probably sit with the patient and tell them if that's the issue, then I would have to make that groin incision and approach it that way to make sure we get everything. But it's -- it's one of those things that adds time to the surgery.
Q. So in your case, you can get it. It just adds a little more time to the surgery?
A. Not a little time --
MS. THOMPSON: Object to the form.
BY MR. OTTAWAY:
Q. That's fine. She got her right to object.
A. No. It probably takes about an hour on each side.
Q. Okay. It adds an hour more?
A. On each side.
Q. Per side?
A. Yeah.
Q. Anything else?

Page 145

A. To remove that mesh?
Q. Yes.
A. Well, you may be left with the consequences that despite you doing all that surgery, the nerve is still scarred and the pain wouldn't go away.
Q. Have you done a study, Doctor, to determine the percentage of patients or can you refer to one in the literature that you rely upon today --
A. Uh-huh.
Q. -- that discusses the percentage of patients who will have that residual mesh or suffer a consequence from it?
MS. THOMPSON: Object to form.
THE WITNESS: Pardon me?
MS. THOMPSON: Object to form of that question.
THE WITNESS: Yeah.
MS. THOMPSON: It's compound.
THE WITNESS: Yeah, there are studies -- again if you want me to name it, I have to look at the whole article and find it for you. But there are studies

Page 146

showing that most people who are taken to the operating room for removal of mesh are taken to the operating room more than one time for that mesh removal.

BY MR. OTTAWAY:

Q. Okay. And does that apply to mesh in general or TVT-O or TOT devices in specific?

A. The literature is mixed about that. They put them together, but they're utilizing the same space.

Q. Okay. But, again, my question was: I want to know if you have or cite to anything that shows us the number of people who will continue to have difficulties if the mesh you've just talked about --

A. Uh-huh.

Q. -- that you have to get at through the groin incision --

A. Uh-huh.

Q. -- remains in place.

A. Yeah. So -- so the -- our experience is that if the patient comes with groin pain, pain going inside their thigh, etc., their management is different with somebody whose

Page 147

mesh is eroding through. Where if they're eroding through, we go as far as we can and we remove it versus if they have that thigh pain, we truly try to remove all the mesh that there is. Because in our experience, they would come back and they would have the pain.

Q. Okay. And having removed all of the mesh there is, what is your experience with the relief of symptoms relating to groin or thigh pain?

A. Really mixed because as I said, the nerve can be scarred and there's no way to free it up, but we owe it to the patient who -- who may be facing a life of chronic pain forever to do the best we can to relieve them of pain.

Q. Well, my question is: Doctor, having done the best you can, do you have some kind of reference or can you point me to something that tells me what percentage of patients will have their pain relieved and which percentage won't?

A. It's my personal experience, my professional opinion that -- that when I take them to the OR and I remove the mesh, we cannot

Page 148

predict whose pain goes away and more likely than not their pain may not go away because of the scarring in that area.

Q. Okay. So I want to -- I want to understand what you're telling me here.

Are you telling me that more than 50 percent of the time their pain will not go away?

You take them to surgery, you do everything you've just described, and it doesn't help a bit.

MS. THOMPSON: Object to form.

THE WITNESS: True.

BY MR. OTTAWAY:

Q. Okay. And have you published those results or have others published results that are consistent with that?

A. I have to look. I recall having seen things in the literature, but I have to search for it.

Q. Okay. You can't just tell me that it's in your reliance materials in B?

A. I generally use a computer program to look these things up. That's why looking at this for me is difficult for me.

Page 149

Q. I --

A. This is not the form I created. So, but I can in terms of, you know, in terms of an add to me, I think there was -- I mean, if you really want names, if you go to like TO on page -- let's see.

So that's on page 74 of clinical literature reference list where they had a randomized trial of TVT versus TVT-O, and they -- they prematurely aborted this study because they had like 26 percent pain problem.

And then the -- if you want names, Spinosa. Let me just see.

Q. I want to make sure we're talking about the same thing.

I'm talking about people who have had a patient come in --

A. Uh-huh.

Q. -- that have had a TVT-O or device that has gone through the obturator space.

A. Uh-huh.

Q. And the surgeon has gone and removed that device.

As I recall, your opinion was that

Page 150

more than half of those patients will continue to have pain, and I want to make sure those studies address that.
A. I think --
Q. Or is that just your experience?
A. No. I think people like me that have wide disparate understanding and professional experience, not only me.
I think if you look at Rogo-Gupta Raaz's paper on page 64, that would -- that would point you to that direction and that opinion.
Q. Okay. Anything else? Anybody else that you want to reference that comes to mind as you look through your Exhibit B?
A. I think to reinforce the anatomical reliability of the course of physics, if you look at the Spinosa, that would be a good one. That would show you that how variable the course of these TVT-O tapes are. And that would be on page -- where is Spinosa? Page 71. That would be a good one.
The -- whatever else? Yep, that's a good one, too. So also if you look on page 33, Hinoul, H-i-n-o-u-l, talks about the anatomical

Page 151

variability and the trajectory of the TVT devices and how they're going into the spaces they shouldn't.
So that supports really what we are saying in terms of being in a space where there are nerves and entraption of the nerve, and scarring and pain that comes with it.
Q. Okay. Thank you, Doctor.
Take a brief break here and we'll be done in nine minutes.
THE VIDEOGRAPHER: Time now is --
MS. THOMPSON: I have -- do you need a break for the tape? I don't have very long if we want to go ahead and go through.
MS. FISCHER: We're not finished. We're taking a --
MR. OTTAWAY: No. You can -- as far as I'm concerned --
MS. THOMPSON: Oh, okay.
MR. OTTAWAY: -- she can ask and I'll follow up, I mean, for nine minutes.
MS. THOMPSON: Okay. You have nine minutes left?

Page 152

MR. OTTAWAY: Roughly yes.
MS. THOMPSON: Okay. We'll take a break and you can come back and do your nine minutes. And then I have some redirect.
THE VIDEOGRAPHER: We are going off the record at 1:41.
(Recess - 1:41 p.m. - 1:49 p.m.)
THE VIDEOGRAPHER: Time now is 1:49. We are back on the record. This is the beginning of disk No. 3.
BY MR. OTTAWAY:
Q. Doctor, you've referenced several times pain associated with TVT-O and TOT devices.
And when you referenced that pain, are you specifically referring to leg and groin issues?
A. Patients generally start with leg and groin pain. That is supposedly can be transient and then -- but it stays then become chronic. Like any other type of pain, it can -- can become systematic, become chronic pain syndrome.
Q. But outside the chronic pain

Page 153

syndrome area, we're talking about leg and groin specifically?
A. Well, they present in very -- many different variations which go back to question you had, how do you differentiate between different pains? Because you -- if you're lucky, you get them if they just have that pain, but if it has expanded and it includes more systems, then you have to sift through it and see what comes from where.
Q. Doctor, you referenced an FDA 2011 bulletin in your report.
That bulletin doesn't apply to mid-urethral slings used for stress urinary incontinence, does it?
MS. THOMPSON: Object to form.
THE WITNESS: What's the question?
BY MR. OTTAWAY:
Q. The report you referenced, the FDA report at 2011 --
A. Uh-huh.
Q. -- doesn't refer to mid-urethral slings, does it?

Page 154

MS. THOMPSON: Object to form.
THE WITNESS: I have to look at it. I -- you know, they have had a few warnings.
BY MR. OTTAWAY:
Q. Okay. You're just not aware without looking at it?
A. I know the 2008 one did.
Q. Right.
A. And they put them together and I know the more recent one that they had didn't, but I'm not quite sure whether it was 2008 or '9.
Q. Okay. You talked about patient anatomy, Doctor.
Isn't patient anatomy always an issue when you're doing surgery?
A. Patient anatomy. I think I was talking about the anatomical region of the body --
Q. Right.
A. -- not the patient themselves.
Q. But isn't patient anatomy something you always consider before you do surgery? It's always a factor, isn't it?

Page 155

A. Well, as surgeons, we are talking about the anatomical regions of the body. So when you -- you want to be familiar with that area when you do the surgeries.
Q. You talked about TVT-O technique --
A. Uh-huh.
Q. -- being perhaps more difficult for some people.
Are you --
A. I'm not sure if I said it was more difficult for some people.
Q. Do you think it's more difficult?
MS. THOMPSON: Object to the form of that.
THE WITNESS: To perform it?
BY MR. OTTAWAY:
Q. Yes.
A. Than what?
Q. That was my going to be my question. Than what?
A. Oh, I see.
I think -- so you're --
Q. Let me just ask it this way, Doctor. I don't want you to struggle with it.

Page 156

Let's talk about non-mesh surgical options for the treatment of stress urinary incontinence, such as Burch procedure or other things.
Would you consider those more difficult or less difficult than the placement of a TVT-O?
A. Depends on the person. I personally can probably do Burches efficiently as TVT or TVT-O.
Q. Okay. So to you, it's roughly the same would you --
A. Well, depends on your team and depends who you're talking to.
Q. Do you have a general idea about which is more difficult?
A. In terms of time, probably the Burch would take more time.
MR. OTTAWAY: All right. That's all I have right now. I'll reserve whatever time I have remaining.
EXAMINATION
BY MS. THOMPSON:
Q. Okay. I have a few questions for

Page 157

you, Dr. Shobeiri.
A. Okay.
MR. OTTAWAY: And I guess let me -- I'm not certainly going to stop you from asking your questions, Margaret, but let me say for purposes of the record, since this is the first one of these we've done, I'm not sure what the protocol is and so I would object to the questioning. But you are certainly free to ask it.
MS. THOMPSON: Okay. And I'll tell you that we've never had any restrictions on redirect questioning by -- by plaintiff's counsel. So, but your objection is on the record.
BY MS. THOMPSON:
Q. Dr. Shobeiri, are all of the opinions in your report supported by the peer-reviewed medical literature?
A. Yes.
Q. And did you provide some examples of that literature supporting your opinions in the body of the report as footnotes?
A. Yes. Not everything, but some of

Page 158

them.
Q. And there are other examples in the 84-page list of references as well?
A. Yes.
Q. So if you would go through the report and look at Footnote 2.
And do those, some of the references in Footnote 2, deal with the opinions that Mr. Ottaway was asking you about earlier?
A. True.
Q. And how about Footnote 3?
A. True.
MR. OTTAWAY: Object to the form of both those questions, but go ahead.
BY MS. THOMPSON:
Q. And --
MR. OTTAWAY: You may answer, Doctor.
BY MS. THOMPSON:
Q. Are the opinions that Mr. Ottaway asked you about earlier supported by Footnote 5?
MR. OTTAWAY: Same objection. May I have a standing objection, counsel?
MS. THOMPSON: Uh-huh. You may.

Page 159

MR. OTTAWAY: Thank you.
MS. THOMPSON: Because I'm going to do several of them.
MR. OTTAWAY: I know you are. As long as you give me a standing objection, I won't make it.
BY MS. THOMPSON:
Q. Okay.
A. True.
Q. And Footnote 7?
A. Yes.
Q. Footnote 8?
A. Yes.
Q. Footnote 14?
A. Yes.
Q. Footnote 17?
A. Yes.
Q. Footnote 22?
A. Yes.
Q. Footnote 23?
A. Yes.
Q. Footnote 25?
A. Yes.
Q. And Footnote 26?

Page 160

A. Yes.
Q. There were also some specific questions regarding literature supporting opinions that you gave here today, and I don't have those articles with me, but these are all contained on your reliance list.
And would you identify this article, please?
A. Sure. This is the "Salvage Surgery After Failed Treatment of Synthetic Mesh Sling Complications" by Dr. Blaivas.
Q. And -- and it's published in what journal?
A. It's -- let me see. This is not the -- okay. There we are. Urology.
Q. And is that a peer-reviewed journal?
A. That's a peer-reviewed journal.
Q. Could you just read that last sentence of that article?
A. Yeah. It goes to the point that I made earlier that generally mesh sling complications repair may require multiple surgeries.
Q. And read the very last sentence of

Page 161

the conclusions in the main report in the main article.
A. This?
Q. This last sentence.
A. So basically what the authors concluded was that the most difficult problem to treat is pain, with only 28 percent of patients with pain considering salvage operation is success.
Q. So does that support your opinion that -- that as many as 50 percent of patients with pain do not get resolution after surgery to remove it?
A. Yes.
MR. OTTAWAY: Objection to the form of the question.
BY MS. THOMPSON:
Q. You also were asked some questions about community doctors and their knowledge of mesh complications?
A. Yes.
Q. And you cited an article that you were one of the authors about Oklahoma.
And are there other articles

Page 162

that address that same issue that you're aware of?
A. Yes.
Q. For example, could you identify this article that is also on your reliance list and then read that highlighted?
A. Sure. So basically this is a journal from the Female Pelvic Medicine Reconstructive Surgery, which is the journal of American Urogyne Society, and the authors -- this is the one that we had quoted Hanson saying that similar to other reports fewer than 50 -- fewer than 25 percent of women were referred by the surgeon that placed their mesh.
This may contribute to the continued use of these products, as the physicians placing them may not be fully aware of their own mesh complications.
Q. And when was that article published?
A. That was I think in 2014 or '15. Let me look. Ah, there we are. 2014.
Q. And could you identify this article, when it was published, and what journal?
A. So let me just see. So the authors

Page 163

here conclude that one of the things they say that there's a management gap in the treatment outcome related to management of mid-urethral sling complications and this was in information in health care. And let me see. It was a review by Lee and Zimmer. And let me just see.
How do you move the screen in? I need to look at the cite.
I need to look at that cite.
Q. It's in Expert Review of Medical Devices.
A. Okay. Yeah. So the Expert Review of Medical Devices in 2015.
Q. And could you read that highlighted part of that?
A. If I can get to there. Was that the one I just -- this one?
Q. Yeah.
A. Okay. So there's a knowledge gap in treatment outcomes related to management of mid-urethral sling complications.
MS. THOMPSON: All right. That's all.
MS. FISCHER: Excuse me. Who is

Page 164

the author?
MS. THOMPSON: Lee.
MR. OTTAWAY: Zimmer and Lee.
BY MS. THOMPSON:
Q. Is nerve pain contained in the instructions for use for the TVT-O?
A. The nerve injury is, but not nerve pain.
Q. And -- well, why don't you get the IFU out.
A. Let me look.
So basically punctures and lacerations of vessels, nerves is included.
Q. And is that referring to punctures and lacerations at the time of surgery?
A. Yes, may require surgical repair.
Q. Can you fix a nerve that's -- can you repair a nerve that's punctured or lacerated at the time of surgery?
A. Major nerves, yes, but not the obturator nerve.
Q. And how would you know that a nerve was punctured or lacerated at the time of surgery?

Page 165

A. The patient would make -- feel numbness or excruciating pain.
Q. Do you remember being asked questions about warnings earlier by Mr. Ottaway?
A. Yes.
Q. Are warnings, the warnings of risks and adverse events, part of the regulatory and legal obligations of a medical device manufacturer?
MR. OTTAWAY: Objection to form.
THE WITNESS: Yes.
BY MS. THOMPSON:
Q. Is knowledge of warnings important to physicians to decide on the best treatment options for a patient?
A. Yes.
MR. OTTAWAY: Objection to form.
BY MS. THOMPSON:
Q. What is informed consent?
A. The informed consent is the discussion we have with the patient to gain their permission to do any procedure for them and let them know of the -- how the procedure is done and how the complications or adverse events may be.

Page 166

Q. And is this something you do as part of your practice on a regular basis?
A. Yes.
Q. Are warnings part of a doctor's need to be able to obtain proper informed consent from patients?
A. Yes.
Q. Do you have an opinion as to whether a doctor can obtain informed consent from a patient if he or she is unaware of the known risks associated with a particular treatment?
A. They cannot.
MS. THOMPSON: That's all I have.
FURTHER EXAMINATION
BY MR. OTTAWAY:
Q. Doctor, you were shown some literature. I'd like to lay four things in front of you and ask if these are on your reliance list.
A. It was -- all right. Let me just look. Let me ascertain because a lot of these people publish a lot of different. So that's from 2012.
(Reviewing document).

Page 167

MR. OTTAWAY: Let's go off the record while you look and see, Doctor. I don't want to burn the record time here while you look.
THE VIDEOGRAPHER: Time now is --
THE WITNESS: For the first one that you have I don't --
THE VIDEOGRAPHER: -- 2:05. We're going off the record.
(Recess - 2:05 p.m. - 2:14 p.m.)
BY MR. OTTAWAY:
Q. Doctor, we went off the record a minute ago so I could show you a couple of articles and ask you if they were on your reliance list.
A. Uh-huh. Yes.
Q. I think you discovered they were not; correct?
A. One of them was not.
Q. Yeah. So let me hand you a randomized trial of tension-free vaginal tape from the Journal of Urology published in 2011, and this is one of the publications I asked you about early on in your deposition, and just ask

Page 168

you to read the conclusion of the authors in that study.
A. So this is a paper by Teo from Journal of Urology. Okay.
"Short-term cure rates at six months are similar for the two procedures. TVT-O resulted in higher levels of postoperative leg pain. Also these problems were transient. Our findings are similar to those in other studies comparing retropubic and transobturator tapes. The two procedures have a high cure rate with a low rate of complications."
Q. Doctor, let me hand you what I'll tell you is "TVT-O for the treatment of pure urodynamic stress incontinence efficacy, adverse effects, and prognostic factors at 5-year follow-up" published in the European Urology Journal in 2013, and ask you to read the conclusion in that study.
A. So I think this was the one that was in the reliance list. So -- so this is a 5-year follow-up. Let me just see whether they are -- maybe it's mislabeled. 930.
I mean, I have seen this study, but

Page 169

there --
Q. I just asked you to read the conclusion of the study for the ladies and gentlemen.
A. So the page numbers are not the same and so okay.
So basically what they're saying is that the:
"TVT-O implantation is a highly effective opinion option for the treatment of women with pure SUI showing a very high cure rate and low incidence of complication after 5-year follow-up."
And that was Serati, pages 872 to 878, 2008. '13.
Q. And, Doctor, I'll hand you, finally, what is an article from the International Urogynecological Journal of 2014, which is Seven years of objective and subjective outcomes of trans -- say that word for me again.
A. Which one are you reading? Transobturator.
Q. -- transobturator (TVT-O) vaginal tape." That's what we've been talking about, and

ask if you would read the conclusion of that study at page 224.

It starts "In conclusion." It's the last paragraph of the study.

A. Okay. Yes. So:

"In conclusion, this study supports the long-term TVT-O outcomes using a retrospective design in a real life cohort. It shows that the TVT-O procedure provides for high long-term efficacy clinically meaningful improvement in patients' quality of life and an excellent safety profile. However, women with central compartment prolapse in those undergoing concomitant vaginal hysterectomy had a higher risk of subjective failure. These results could therefore be useful to clinicians for preoperative consultation."

Q. Thank you, Doctor. That's all I have.

A. Thank you.

MS. THOMPSON: I have one more question.

FURTHER EXAMINATION

BY MS. THOMPSON:

Q. Dr. Shobeiri, did you consider and critically assess literature that was both favorable and unfavorable to your opinions?

A. Yes, I did.

MS. THOMPSON: That's it.

MR. OTTAWAY: You have the right to read and sign this deposition, Dr. Shobeiri, and you should consult with Margaret and see what you wish to do.

MS. THOMPSON: You will.

THE WITNESS: Thank you.

THE VIDEOGRAPHER: The time now is 2:19. This deposition has concluded.

(Signature having not been waived, the taking of the deposition concluded at 2:19 p.m.)

* * *

CERTIFICATE OF COURT REPORTER

UNITED STATES OF AMERICA)

COMMONWEALTH OF VIRGINIA)

I, DENISE D. VICKERY, the reporter before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was sworn by me; that the testimony of said witness was taken by me in machine shorthand and thereafter transcribed by computer-aided transcription; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken; and, further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, or financially or otherwise interested in the outcome of this action.

Notary Public in and for the
Commonwealth of Virginia
My Commission expires March 31, 2018 ID - 126014

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

E R R A T A

PAGE LINE CHANGE

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

WITNESS NAME DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

_____

Notary Public

LAWYER'S NOTES

PAGE LINE

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____